Tort Law and Technology

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Many commentators argue that tort law is inappropriate for responding to the risks posed by emerging technologies. Courts are often seen as technically incompetent, and the case method is criticized for sending haphazard signals to producers. Administrative agencies, it is argued, have greater expertise than courts, and their capacity for uniform rulemaking allows them to create a stable legal environment that contributes to technical progress and economic growth. These criticisms seem to justify current trends in preemption of tort law—Congress has been considering measures to restrict tort law, and courts are increasingly finding tort law preempted, even in the absence of explicit legislation to that effect.

Professor Lyndon argues that tort law plays a valuable role in the management of new technologies. By giving producers incentives to concern themselves with all harms that a new technology may cause, rather than just those that a regulatory agency identifies, tort law encourages broader and more effective consideration of safety issues. In addition, knowledge of the specific context in which alleged harms were suffered may be critical in deciding how to react to those harms. The case method allows a more detailed consideration of this context. The focus of legal reform, Professor Lyndon argues, should not be on preempting on tort law, but on determining how tort law, regulation, and intellectual property law can best complement one another to allocate the burdens and benefits presented by technological change.

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Introduction

Does tort law have a part to play in controlling the side effects of technologies? Some scholars argue on economic grounds that regulation is preferable to tort law, that legislatures should not hesitate to preempt common law causes of action, that courts should be liberal in finding implied preemption, and that courts should reverse the common law rule that a regulatory permit is not a defense to tort liability.[1] Regulation should generally replace liability, they argue, "preempting" tort law as the basic legal response to technologies which generate health, safety, and environmental risks.[2]

Tort law's critics argue that liability is superfluous, especially where an administrative agency has engaged in a cost-benefit analysis of a particular

1. The literature which examines the relative capacities of the regulatory and liability systems contains a variety of viewpoints on the value of tort law. Some authors are particularly interested in modifying or curtailing tort law's reach. *See, e.g.*, AMERICAN LAW INST., REPORTER'S STUDY ON ENTERPRISE LIABILITY FOR PERSONAL INJURY ch. 3 (1991); SUSAN ROSE-ACKERMAN, RETHINKING THE PROGRESSIVE AGENDA ch. 8 (1992); PETER SCHUCK, AGENT ORANGE ON TRIAL (1986); TORT LAW AND THE PUBLIC INTEREST (Peter Schuck ed., 1991); Susan Rose-Ackerman, *Environmental Liability Law*, *in* INNOVATION IN ENVIRONMENTAL POLICY (T.H. Tietenberg ed., 1992); *see* PETER HUBER, LIABILITY—THE LEGAL REVOLUTION AND ITS CONSEQUENCES (1988); THE LIABILITY MAZE (Peter Huber & Robert E. Litan eds., 1991); W. KIP VISCUSI, REFORMING PRODUCTS LIABILITY (1991); Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 229 (1985) [hereinafter Huber, *Safety and the Second Best*]; W. Kip Viscusi, *Toward a Diminished Role for Tort Liability: Social Insurance, Government Regulation, and Contemporary Risks to Health and Safety*, 6 YALE J. ON REG. 65 (1989) [hereinafter Viscusi, *Diminished Role*]; W. Kip Viscusi, *Wading Through The Muddle of Risk Utility Analysis*, 39 AM. U. L. REV. 573 (1990). This position has not, however, found universal favor. *See* Mark M. Hager, *Civil Compensation and Its Discontents: A Response to Huber*, 42 STAN. L. REV. 539 (1990) (criticizing THE LIABILITY MAZE); Joseph A. Page, *Deforming Tort Reform*, 78 GEO. L.J. 649 (1990). An interesting perspective on the overall debate is presented in Peter L. Kahn, *Regulation and Simple Arithmetic: Shifting the Perspective on Tort Reform*, 72 N.C. L. REV. 1129 (1994). Kahn argues that the costs and benefits of regulations usually are inflated because estimates do not treat regulation as an addition to the tort system's influence on risk-generating activities. Kahn views tort law's influence as considerably broader and more intense than regulation's. He proposes enhancing both systems by designing regulations that take account of and support the tort system. *See infra* part III.

2. This is not a preemption issue as the term is usually understood in the legal context. Although sometimes the legal issue presented is a question of the effect of a federal regulation on state common law, the real issue in the context of tort reform is regulatory versus judicial management of the specific subject. *See infra* part III. For the doctrinal framework of this debate, see Teresa Moran Schwartz, *The Role of Federal Safety Regulations in Products Liability Actions*, 12 J. PROD. LIAB. 305, 319-29 (1988).

technology's risks. They argue that agencies, due to their specialized knowledge, are better qualified to deal with technical subject matter. Tort law undermines regulation, in this view, by imposing on firms a superfluous and disorganized second layer of legal controls.[3]

The preemption argument has begun to influence the decisions of lawmakers and courts. Congress has been considering bills containing uniform products liability standards, including the preemption of punitive damages where drugs and medical devices have been approved by the Food and Drug Administration (FDA).[4] In a 1991 report, the American Law Institute proposed a broad reversal of the common law rule that a regulatory permit is not a defense to liability. The report was not adopted, but similar proposals are being considered in the preparation of the *Restatement (Third) on Products Liability*.[5]

A recent wave of court decisions on preemption seems to be a related trend. The Supreme Court's 1993 decision in *Cipollone v. Liggett Group* has signalled to courts that statutory preemption provisions should be read broadly.[6] In that case, the Court read the Federal Cigarette Labelling Act's express preemption language to preclude some common law causes of action.[7] Finding similarities in the language of other preemption provisions, courts are

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3. Rose-Ackerman argues that treating statutes and regulation as minima destroys uniformity and substitutes the judgment of less knowledgeable judges and juries for that of agencies. *See* Susan Rose-Ackerman, *Tort Law in the Regulatory State, in* TORT LAW AND THE PUBLIC INTEREST, *supra* note 1; *see also* AMERICAN LAW INST., *supra* note 1, at 86-89.

Others see tort law as a more valuable supplement to agency regulation and courts as able to use information which is not available to agencies. *See, e.g.*, Steven Shavell, *Liability for Harm Versus Regulation of Safety*, 13 J. OF LEGAL STUD. 357 (1984) [hereinafter Shavell, *Liability for Harm*]; STEVEN SHAVELL, ECONOMIC ANALYSIS OF ACCIDENT LAW 277-90 (1987) [hereinafter SHAVELL, ECONOMIC ANALYSIS]. Shavell suggests that in general, knowledge factors favor regulation, but where private parties have superior information, it is better for them to decide how to control risks; the reverse is true where regulators have better information. *See* Shavell, *Liability for Harm*, *supra*, at 357; SHAVELL, ECONOMIC ANALYSIS, *supra*, at 285-86.

4. S. 687, 103d Cong., 1st Sess. § 203 (1993); H.R. 1910, 103d Cong., 1st Sess. § 6(d) (1993). These efforts are likely to be more successful in coming legislative sessions, since key opponents of liability limitations were defeated in the 1994 elections. *See* Milo Geyelin and Richard B. Schmitt, *Liability Reform Buoyed by GOP Win*, WALL ST. J., Nov. 11, 1994, at B5.

5. AMERICAN LAW INST., *supra* note 1, ch. 3; Michael Hoenig, *The American Law Institute Restatement Draft*, N.Y. L.J., May 9, 1994, at 3.

6. Cipollone v. Liggett Group, Inc., 112 S. Ct. 2608 (1992). Kahn, *supra* note 1, surveys the results of *Cipollone* at 1146-49.

7. *Cipollone*, 112 S. Ct. at 2622-24. The *Cipollone* Court held that some of the plaintiff's claims were preempted by 15 U.S.C. § 1334(b), which provides that "[n]o requirement or prohibition based on smoking or health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of the Act." The Court framed the preemption inquiry as "whether the legal duty that is the predicate of the common law damages action constitutes a 'requirement or prohibition based on smoking and health . . . imposed under State law with respect to . . . advertising or promotion . . . .'" It held that the implied warranty and failure to warn claims arose out of advertising and promotion and were expressly preempted, while the claims for fraud, express warranty, and conspiracy were not preempted.

now more freely dismissing claims for injuries, particularly claims relating to pesticides[8] and medical devices,[9] including products as diverse as collagen implants,[10] heart valves and pace makers,[11] and ocular lens implants.[12] These cases have not considered the concrete effects of removing tort liability from each situation. Rather, relying on the preemption doctrine as a guide, the courts infer or assume that Congress has already done so.

The courts seem drawn to the preemption doctrine in part out of exasperation with the shortcomings they perceive in tort law. When the statutory bases for preemption are less than compelling, the sense that tort law itself is dysfunctional may tip the balance against liability.

But regulation is not perfect either. For instance, the FDA approved the drug diethylstilbestrol (DES) for use during pregnancy, but its limited oversight

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8. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), states that "[a] State shall not impose or continue in effect any requirements for labelling or packaging in addition to or different from those required under this subchapter." 7 U.S.C. § 136v(b) (Supp. V 1993). A number of courts have held that the *Cipollone* reading of the cigarette labelling provision requires the conclusion that Congress intended to preempt liability claims for pesticide injuries. *See* MacDonald v. Monsanto Co., 27 F.3d 1021 (5th Cir. 1994); Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc., 981 F.2d 1177 (10th Cir. 1993); King v. E.I. DuPont De Nemours & Co., 996 F.2d 1346 (1st Cir. 1993); Papas v. Upjohn Co., 985 F.2d 516 (11th Cir. 1993); Shaw v. Dow Brands, Inc., 994 F.2d 364, 371 (7th Cir. 1993) (holding that "not even the most dedicated hair splitter" could distinguish the two preemption provisions of FIFRA and the Cigarette Act, and that the tort claims in question were expressly preempted); Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc., 959 F.2d 158 (10th Cir. 1992); Papas v. Upjohn Co., 926 F.2d 1019 (11th Cir. 1991); Jillison v. Vermont Log Bldgs., Inc., 857 F. Supp. 985 (D. Mass. 1994); Kenepp v. Am. Edwards Labs., 859 F. Supp. (E.D. Pa. 1994). *But see* Wisconsin Pub. Intervenor v. Mortier, 111 S. Ct. 2476 (1991) (finding no preemption of municipal control over spraying of pesticides in light of FIFRA's express authorization in section 136v(a) for state regulation which does not permit any sale or use prohibited by statute).

9. Such preemption is based on the Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act §§ 521, 521(a) (1988) (codified as amended at 21 U.S.C. §§ 360k, 360k(a)). *See infra* notes 115-16 and accompanying text.

10. *See* King v. Collagen Corp., 983 F.2d 1130 (1st Cir. 1993). The plaintiff in *King* developed autoimmune disease after injection of the collagen implant Zyderm. Her strict liability, breach of warranty, negligent design and manufacture, misbranding, misrepresentation, failure to warn, and fraudulent obtaining of FDA approval claims were all found preempted. *Accord* Stamps v. Collagen Corp., 984 F.2d 1416 (5th Cir. 1993); *see also* Tucker v. Collagen Corp., 1994 U.S. Dist. LEXIS 3101 (N.D. Ill. Mar. 16, 1994). In *King* the court went beyond the *Cipollone* decision to find preemption of claims that the defendant had withheld data from the FDA. In *Cipollone* the Supreme Court expressly found that a common law fraud claim based on allegations that a person withheld information from an administrative agency is not preempted. 112 S. Ct. at 2623-24.

11. *See* Mendes v. Medtronic Inc., 18 F.3d 13 (1st Cir. 1994) ("MDA reflects Congress's balancing the need for regulation to protect public health against its interest in allowing new and improved devices to be marketed expeditiously without the costs attributable to excess regulation."); Bravman v. Baxter Health Corp., 842 F. Supp. 747, 760-61 (S.D.N.Y. 1994) (recognizing the reasons opposing preemption, including fact that tort remedy provides incentives to continue product improvement and that preemption leaves plaintiffs without a remedy and encourages manufacturers not to disclose, but finding that a careful reading of FDA's regulations compelled conclusion that claims dealing with Class III medical devices are expressly preempted); Griffin v. Medtronic, Inc., 840 F. Supp. 396 (D. Md. 1994); Kemp v. Pfizer, 851 F. Supp. 269 (E.D. Mich. 1994); Michael v. Shiley, Inc., 1994 U.S. Dist. LEXIS 1973 (E.D. Pa. 1994).

12. MDA preemption of state common law has also been found in the area of the FDA's "investigational device exemption regulations." Gile v. Optical Radiation Corp., 22 F.3d 540 (3rd Cir. 1994); Slater v. Optical Radiation Corp., 461 F.2d 1330 (7th Cir. 1992). *See infra* part III.

missed serious omissions in the initial research.[13] The seeds of the DES disaster were planted several decades ago, but the same kind of problem persists today. One pacemaker which was on the market in the mid 1980s tended to malfunction at temperatures above normal body temperature. The FDA approved the device without objecting to the fact that it had not been fully tested for body temperatures above normal.[14] Pharmaceutical firms also failed to forward to the FDA doctors' reports of adverse symptoms from breast implants.[15] A preemption rule, which is a basis for dismissing an action before discovery, removes the possibility that tort plaintiffs may uncover this kind of violation. There are other cases in which serious health problems could have been identified earlier through the tort system.[16]

Before we conclude that tort law's day has passed, we should more clearly understand its functions and capabilities. There has been little analysis of the characteristics of technology which make deterrence a difficult task both for courts and for agencies. This is true in part because of the way most analyses frame the information issues. Lack of information about the effects of technologies is the chief factor limiting our ability to manage them. Decision making under conditions of uncertainty is therefore seen as the central dilemma of the law concerned with health, safety, and environmental (HSE) costs to society. The importance of this problem tends to dominate our attempts to understand both tort law and regulation.

In fact, however, uncertainty does give way to knowledge over time. Society learns as it produces and assembles information about technological hazards.[17] Tort law and regulation are necessarily concerned with encouraging this learning process. Indeed, risk management is both a response to and an influence on the quality and amount of risk information that is available.[18]

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13. The FDA approved DES for use during pregnancy although manufacturers had not performed tests on pregnant mice. Such research would have shown that the drug had the potential to cause cancer in female offspring. Bichler v. Eli Lilly & Co., 436 N.E.2d 182, 185 (N.Y. 1982). The *Bichler* court noted that more complete and thorough research could easily have revealed the dangers associated with DES' being ingested by pregnant women.

14. *See* Larsen v. Pacesetter Sys., Inc., 837 P.2d 1273, 1278-79 (Haw. 1992).

15. The FDA requires firms to forward reports they receive about adverse reactions, but this rule is often not obeyed. Thomas M. Burton, *Law Concerning Medical Devices Is Often Ignored*, WALL ST. J., May 2, 1994, at B1; Teresa Moran Schwartz, *supra* note 2, at 331.

16. For instance, the asbestos cases can be viewed as a failure to apply the liability system to the first indications of the developing health problem. *See infra* subsection I.B.2. *See also* Teresa Moran Schwartz, *supra* note 2, at 347 n.203.

17. Mark Cantley, *Commentary*, *in* THE SUSTAINABLE DEVELOPMENT OF THE BIOSPHERE 348, 349 (William C. Clarke & R.E. Munn eds., 1986) (using term "societal learning"). As each new technology develops, knowledge about its effects emerges. Private research and development, legal screening, market performance, and use in homes, workplaces and other settings constitute a diffuse but potentially coherent social learning process.

18. Carol Rose suggests that environmental management strategies should be adjusted to the state of the resources which are its subject. Carol M. Rose, *Rethinking Environmental Controls: Management Strategies in Common Resources*, 1991 DUKE L.J. 1 (1991). Knowledge likewise can be

Learning and deterrence are thus part of the same legal function. The learning function in the law deserves greater attention.

This Article examines the roles of tort law and regulation within the context of unfolding knowledge about technologies. In particular, it argues that prevailing economic critiques of tort law take insufficient account of the way in which scientific and technical knowledge is actually produced.[19] Innovation economics, which studies the dynamics of private research and development (R&D), is precisely concerned with recognizing and developing new technical knowledge. Intellectual property law addresses the same problem. Recent work in both disciplines sheds light on the problem of designing an effective deterrence mechanism to manage health and safety risks.

Part I of the Article outlines a framework for evaluating the legal deterrence function, drawing on current work in innovation economics and intellectual property. Part II looks at the ways the regulatory system and tort law handle the task of learning about the side effects of technologies. Part III presents some suggestions for coordinating the liability and regulatory systems, using some principles of intellectual property law as a guide.

Preempting tort law is increasingly touted as a way to simplify and manage risks. Yet if we focus on deterrence as a central task of the law, we see that confidence in regulation as a perfect replacement for tort law is surely unwarranted. In addition to its design limitations, regulation is difficult to implement. Regulatory agencies have a mixed record of achievement.[20] Even

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seen as a common resource and patterns in its development can be identified and used in managing it. *See* Mary L. Lyndon, *Information Economics and Chemical Toxicity: Designing Laws to Produce and Use Data*, 87 MICH. L. REV. 1795 (1989) [hereinafter Lyndon, *Information Economics*]; Mary L. Lyndon, *Secrecy and Innovation in Tort Law and Regulation*, 23 N.M. L. REV. 1 (1993) [hereinafter Lyndon, *Secrecy and Innovation*].

19. Most critiques of tort law are based upon the microeconomic model of neoclassical economics. Standard microeconomic analysis, however, does not directly address the way technology and its externalities develop. *See* RICHARD R. NELSON & SIDNEY G. WINTER, AN EVOLUTIONARY THEORY OF ECONOMIC CHANGE 24-30 (1982). Nelson and Winter argue that the neoclassical perspective tends to limit our appreciation of the diversity which is revealed in studies of technical change in different sectors. This in turn affects the treatment of knowledge and information problems: the neoclassical perspective tends to miss the way in which past choices obscure other options. An important result is that the quality and complexity of learning opportunities may be missed. "The problem with the neoclassical metaphor . . . is not that it connotes purpose and intelligence, but that it also connotes sharp and objective definition of the range of alternatives confronted and knowledge about their properties. Hence, it misleadingly suggests an inevitability and correctness in the decisions made . . . ." NELSON & WINTER, *id.* at 250. *See also* W.L.F. Felstiner and Peter Seligman, *Neoclassical Difficulties Tort Deterrence for Latent Injuries*, 11 LAW & POL'Y 309 (1989) (criticizing comparisons of liability and alternatives which start from theoretical claims, rather than from descriptions of how the tort system actually functions).

20. Tort law's critics overestimate agency capacities to recognize and cope with technical problems. Some of the criticisms leveled against courts also apply to administrative agencies; furthermore, agencies also have their own shortcomings, not shared by courts. *See* PETER CLEARY YEAGER, THE LIMITS OF LAW—PUBLIC REGULATION/PRIVATE POLLUTION (1991) [hereinafter YEAGER, LIMITS OF LAW; PETER CLEARY YEAGER, MANAGING LEVIATHAN: ENVIRONMENTAL POLITICS AND THE ADMINISTRATIVE STATE (Robert Paehlke & Douglas Torgerson eds., 1990); Clayton P. Gillette & James E. Krier, *Risk, Courts and Agencies*, 138 U. PA. L. REV. 1027 (1990); Donald T. Hornstein,

the FDA, which is designed to have stronger powers than most health and safety agencies, has missed signs of serious health problems.

Neither tort law nor regulation alone is a sufficient response to these problems. Neither can remove the need to make decisions under uncertainty. Tort law, however, can encourage private accountability for the value of information to society as a whole. The liability system supplements regulation. Together, the two respond to serious shortcomings in the market's production of information. Indeed, the two types of law can best be thought of as branches of health and safety law, which provide different procedural options or formats for addressing the social costs of technical change. Coordinating them to take advantage of their particular strengths should be a focus of both tort and regulatory reform.

I. Knowledge Production and Risk Management

Products and technologies vary widely, but there are some recognizable patterns in their development. Recent work on innovation provides a description of the way technical knowledge is produced. This part first highlights some insights from this literature and then uses these to explore the functions that health and safety law should perform in guiding technical change. Ideally, technologies should come to the market with minimal side effects, all of which are well understood. When this is not possible, early development of risk information is still desirable. Using the innovation literature, we can better identify deterrence and learning opportunities.

A. *The Dynamics of Technical Change*

Economic research on innovation has attempted to identify the forces that shape R&D efforts in an industry. Three lines of inquiry have dominated this field. The first identifies demand, that is, the extent of the market for real improvements and new products, as a major factor in R&D investment and technological change.[21] The second has emphasized the role of supply, that is, innovation opportunities in particular technologies and the existence of underlying social support for investment, including the state of the sciences, the education system, and financial conditions affecting investment.[22] The

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Reclaiming Environmental Law: A Normative Critique of Comparative Risk Analysis, 92 COLUM. L. REV. 562 (1992); Teresa Moran Schwartz, *supra* note 2, at 333-46.

21. *See* JACOB SCHMOOKLER, INVENTION AND ECONOMIC GROWTH (1966); PARTHA DASGUPTA & PAUL STONEMAN, ECONOMIC POLICY AND TECHNOLOGICAL PERFORMANCE 7-8 (1987); NATHAN ROSENBERG, INSIDE THE BLACK BOX—TECHNOLOGY & ECONOMICS 18 (1982) [hereinafter ROSENBERG (1982)]; Morton I. Kamien & Nancy L. Schwartz, *Market Structure, Elasticity of Demand and Incentive to Invent*, 13 J.L. & ECON. 241 (1982).

22. This work is relevant to the concern that tort law has a dampening effect on innovation.

third line of research has investigated the factors affecting appropriability, that is, the investor's ability to secure returns on investment in research.[23] This work examines the R&D behavior of firms and therefore has much to tell us about how technical development is conducted in the private sphere.

The foundation of the appropriability work is a set of assertions, articulated in the early 1960s, which emphasize the scarcity of information and the uncertainty of returns from investments in research.[24] Patent law, according to this view, attempts to encourage investment in learning by granting assured appropriability in the form of a legal monopoly. The patent has long been thought of as a reward to the first inventor,[25] but recent work suggests that this model oversimplifies the situation. The significance of the patent as an incentive and the importance of discrete acts of invention to the larger process of innovation have been questioned. Recent studies suggest that, in order to understand technical change, it is necessary to look at the network of relationships in which inventions are embedded.

For example, the diffusion of information may be more important for technical development than are single acts of invention. When information can spread easily, leading innovative industries produce useful externalities for related industries. As advances fan out, well-positioned firms can exploit new information.[26] Indeed, patent monopolies may reduce innovation by restricting the spread of knowledge, which fuels technical development.[27]

According to this research, better social conditions for innovation can compensate for any such effect. *See* NATHAN ROSENBERG, PERSPECTIVES IN TECHNOLOGY (1976); *see also* DASGUPTA & STONEMAN, *supra* note 21, at 8. Rosenberg suggests that a useful theory of innovation must identify the supply factors that focus innovative search upon certain solutions and must explicitly consider the institutional structures and dynamics which affect the process of achieving solutions. ROSENBERG, *supra*, at 194-95. General economic strength—flexibility in the economic system, educational quality, and rate of investment—is a prerequisite to national capability in high-technology industries. Another key is a system of scientific and technical education that trains well and points a substantial number of graduates toward industrial careers. RICHARD R. NELSON, HIGH TECHNOLOGY POLICIES—A FIVE NATION COMPARISON 4-5, 66-67 (1984); *see also* DAVID C. MOWERY & NATHAN ROSENBERG, TECHNOLOGY AND THE PURSUIT OF ECONOMIC GROWTH 294-95 (1989).

23. Some of this work focuses on industry structure and market concentration and some on intellectual property issues. *See* Wesley M. Cohen & Richard C. Levin, *Empirical Studies of Innovation and Market Structure, in* 2 THE HANDBOOK OF INDUSTRIAL ORGANIZATION 1059, 1073-74, 1090-95 (Richard Schmalensee & Robert D. Willig eds., 1989).

24. *See* Kenneth Arrow, *Economic Welfare and the Allocation of Resources for Invention, in* THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS 609, 614-19 (National Bureau of Economic Research ed., 1962).

25. According to this view, the monopoly slows the process of imitation, increases the costs of copying, and facilitates licensing, so innovators have a chance to recoup their investments.

26. ROSENBERG (1982), *supra* note 21, at 55-56. Richard Nelson also stresses the importance of diffusion, arguing that "[i]ndividual technological advances seldom stand alone. Almost always they connect economically and intellectually to earlier advances and to advances in other but related technologies." NELSON, *supra* note 22, at 6.

27. PAUL STONEMAN, THE ECONOMIC ANALYSIS OF TECHNOLOGY POLICY 51 (1987) [hereinafter STONEMAN, TECHNOLOGY POLICY]. For a description of the literature on diffusion, see PAUL STONEMAN, THE ECONOMIC ANALYSIS OF TECHNOLOGICAL CHANGE 74-122 (1983) [hereinafter STONEMAN, TECHNOLOGICAL CHANGE]. In general, from the point of view of society's interest in

The power of patents as an incentive for encouraging R&D investment has also been questioned.[28] While patterns vary in different technologies and industries,[29] appropriability rests on a number of factors which appear to be stronger than legal influences. These factors include opportunities to gain lead time and exploit learning curve advantages, complementary investing in marketing and customer service, and establishment of trade names.[30] Getting

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maximizing the productivity of information, diffusion should take place as early as possible, because information spillovers may reduce wasteful duplication of R&D effort. *See* ROSENBERG (1982), *supra* note 21, at 55-56; *see also* WILLIAM D. NORDHAUS, INVENTION, GROWTH, AND WELFARE: A THEORETICAL TREATMENT OF TECHNOLOGICAL CHANGE (1969).

28. Economists dispute the usefulness of patents and the type of patent coverage which may be appropriate. Overviews of the literature are given by Sidney G. Winter, *Patents in Complex Contexts: Incentives and Effectiveness*, *in* OWNING SCIENTIFIC & TECHNICAL INFORMATION 41-60 (Vivian Weil & John W. Snapper eds., 1989) and Steven Cheung, *Property Rights and Invention*, 8 RES. L. & ECON. 5 (1986).

Kenneth Arrow has suggested that without the legal protection of patents, the level of investment will always be too low. Kenneth Arrow, *Economic Welfare and the Allocation of Resources for Invention*, *in* THE RATE AND DIRECTION OF INVENTIVE ACTIVITY 609 (1962); *see also* Jennifer F. Reinganum, *The Timing of Innovation: Research Development and Diffusion*, *in* 2 THE HANDBOOK OF INDUSTRIAL ORGANIZATION, *supra* note 23, at 850.

Others have been concerned, however, that granting monopolies encourages waste. Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 278-79 (1977). Dasgupta and Stiglitz have argued that with a patent system, overinvestment will occur because if a patent is valuable, research efforts will cluster around the particular research obstacle to obtaining the patent, creating "common pool" inefficiencies. *See* Partha Dasgupta & Joseph E. Stiglitz, *Industrial Structure and the Nature of Innovative Activity*, 90 ECON. J. 266 (1980); *see also* STONEMAN, TECHNOLOGY POLICY, *supra* note 27, at 80-84, 96. A related effect may be that patents encourage firms to pursue a narrow range of research projects, while society needs greater diversity.

29. Industries vary significantly in the rate of patents generated by R&D dollars invested. *See* Cohen & Levin, *supra* note 23, at 1076-77. Studies have indicated that patents function well in the chemical and pharmaceutical industries. STONEMAN, TECHNOLOGICAL CHANGE, *supra* note 27, at 15-17. Other studies have suggested that, in industries other than pharmaceuticals, patents are not of vital importance, and that other means of protecting returns are available. *Id.*; *see also* STONEMAN, TECHNOLOGY POLICY, *supra* note 27, at 115-16 ("The moral of this evidence is thus that, despite a long-standing concern over the nature and impact of the patent system, the importance of the system, in practical terms, may not be particularly great.").

30. *See* Richard Levin et al., *Appropriating the Returns from Industrial Research and Development*, *in* 3 BROOKINGS PAPERS ON ECONOMIC ACTIVITY 783, 794-97 (Martin Neil Baily & Clifford Winston eds., 1987). Levin et al. examined 650 responses to questions about what factors were most important in determining appropriability of benefits from investment in new products and processes in 130 different lines of business.

Generally, participants in the survey considered lead time, learning curves, and sales or service efforts at least as effective as patents or secrecy, and many considered them substantially more effective. The results of this survey generally agree with other studies on the topic. Patents were generally rated the least effective mechanism for appropriating processes. Lead time and learning curve advantages were rated the highest. Secrecy was considered more effective for processes than patents, but not as effective as lead time and learning curve advantages. For products, patents were considered more effective than secrecy, but less effective than lead time and learning curve advantages. The data provided some support for the idea that secrecy may be chosen instead of patenting where disclosures in a patent may facilitate inventing around it.

Levin et al. also found that investments in establishing trade names may be more effective and longer-lived than patents. *Id.* at 784; *see also* Meir Statman, *The Effect of Patent Expiration on the Market Position of Drugs*, *in* DRUGS AND HEALTH: ECONOMIC ISSUES AND POLICY OBJECTIVES 140-51 (Robert B. Helms ed., 1981).

the product to market as quickly as possible is often the key to recouping investment. The flow of investment to R&D in general, therefore, is driven by more powerful factors than either liability or regulation.[31]

The reward theory of intellectual property law is further undermined by recognition of the fact that all knowledge is incremental. New information evolves from existing knowledge.[32] Thus, intellectual property law and economics are increasingly going beyond the simple reward theory and concerning themselves with fostering the incremental development of bodies of technical knowledge.[33]

A metaphor that is useful in understanding this project is that of a knowledge "topography."[34] In this conception, knowledge is recognized as having concrete spatial and temporal limitations. Learning takes place over time in a context of existing information and research possibilities. Knowledge contains rich details which create options and affect behavior, including the production of new information. Private R&D takes place in an idiosyncratic and dynamic setting. The structure of each market and the characteristics of each technology are unique. Firms selectively produce and develop knowledge in response to these learning opportunities, reacting to the behavior of rivals[35] who work on related projects in a loosely knit group in the same vicinity of the research terrain.[36]

These results are consistent with the findings of other studies on patent effectiveness; *see* Winter, *supra* note 28, at 45-57.

31. Innovation economists generally do not mention tort liability at all and do not consider the effects of regulation on R&D investment. Richard Nelson and Sidney Winter, however, have considered the influence of legal rules on consumer preferences in the environment in which researchers and investors seek feedback on what will be profitable. Their analysis also considered the benefits and costs to the organizations that are considering adopting the innovation, the relationship between profit and the expansion/contraction of particular organizations or units within the researching firm, the nature of mechanisms by which other organizations learn about innovations of other firms, and the factors that facilitate or deter imitation. NELSON & WINTER, *supra* note 19, at 262-63.

32. *See* Paul M. Romer, *Increasing Returns and Long-Run Growth*, 94 J. POL. ECON. 1002 (1986); Lyndon, *Secrecy and Innovation*, *supra* note 18, at 13-14; Lyndon, *Information Economics*, *supra* note 18, at 1849-55.

33. *See* Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 843 (1990).

34. NELSON & WINTER, *supra* note 19, at 229. Nelson and Winter suggest that "the result of today's searches is both a successful technology and a natural starting place for the searches of tomorrow. There is a 'neighborhood' concept of a quite natural variety." *Id.* at 257. The "topography" metaphor allows a richer description of the cognitive conditions in which the search for new methods takes place. "The topography of innovation determines what possibilities can be seen from what vantage points, how hard it is to get from one spot in the space of possibilities to another, and so forth." *Id.* at 229.

35. Innovations emerge from competition at particular locations on the topography. *See* Reinganum, *supra* note 28, at 904-905; *see also* NELSON & WINTER, *supra* note 19, at 203 (arguing that key differences in outcome are due to luck and differing responses to the same information); *id.* at 250-52.

36. Most of Levin's respondents reported that only three to five firms were capable of duplicating a major process or product innovation and, for a typical process or product innovation, the number was six to ten. Richard Levin et al., *Appropriating the Returns from Industrial Research and Development*, *in* 3 BROOKINGS PAPERS ON ECONOMIC ACTIVITY 783, (Martin Neil Baily & Clifford Winston eds., 1987). These firms are in touch with each other, whether through formal or informal channels. Each

Problems which may arise in this setting include duplication of research efforts and premature exploitation of research results as rivals race for control of a technology.[37] Edmund Kitch has proposed a model of patent law which builds on the notion of a knowledge topography and addresses some of the problems unique to the R&D setting. Kitch has suggested that early patent grants effectively assign stewardship of technological prospects to patentees, allowing opportunities for coordination and reducing duplicated effort in R&D.[38] The patent rewards the inventor for being first and places the management of the prospect in the hands of the inventor, probably the entity best equipped to handle it. This model provides a framework for communication with other interested firms.[39] Patents are granted early in the innovation process and allow firms to signal each other efficiently.[40] Although other authors have questioned the idea that unitary management of technical developments through patent law is more productive than competition, Kitch's model illustrates the shift in intellectual property thinking away from the reward theory and toward a theory concerned with managing complex knowledge and investment resources.[41]

This perspective has much to offer health and safety law. Knowledge issues are generally framed in tort law and regulation only in terms of uncertainty. The fact that information is produced in response to investment is rarely recognized. The Supreme Court of New Jersey's decision in *Beshada v. Feldman* is, however, one exception to this rule. The *Beshada* court denied asbestos manufacturers the "state-of-the-art" defense to strict liability claims. The court reasoned that the industry itself produced the state of the art through its own R&D agenda.[42] This and related developments in tort law and regulation are steps toward a more coherent focus on knowledge as a subject

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firm has an incentive to control access to information about its activities, in order to maximize its edge over its rivals. *See* Reinganum, *supra* note 28.

37. *See* Dasgupta & Stiglitz, *supra* note 28; Yoram Barzel, *Optimal Timing of Innovation*, 50 REV. ECON. & STAT. 348 (1968).

38. Kitch, *supra* note 28, at 278-79. Kitch suggests that, rather than giving rewards to winners in technological races, the patent system functions like the mineral claims system for public lands. It provides the legal setting necessary to allocate resources to the development of a technological "prospect." *Id.* at 269.

39. *Id.* at 278-79. Kitch builds on Barzel's point that the exploitation of technological information is analogous to the exploitation of fisheries, public roads, and oil and water pools, resources which are not subject to exclusive control. Where a rule of first appropriation controls, there is an inefficiently rapid depletion of the resource; it would be more efficient to grant or auction off a monopoly, giving the owner a right to develop the technological opportunity. *See* Barzel, *supra* note 37, at 76.

40. Since most patenting probably occurs before development and since most R&D dollars are spent on development, patents may allow much research to be done openly and in an efficient sequence. *See* Kitch, *supra* note 28, at 276-77; *see also* FREDERIC M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 350 (2d ed. 1980) (over 75% of R&D dollars are spent on development and the initial innovation is typically inexpensive); STONEMAN, TECHNOLOGY POLICY, *supra* note 27, at 109-11.

41. *See* Merges & Nelson, *supra* note 33, at 871-79.

42. Beshada v. Johns Manville Prods. Corp., 447 A.2d 539 (N.J. 1982).

of legal influence. The next section highlights some specific insights from the innovation literature and links these to the concerns of health and safety law.

B. *Deterrence Opportunities in the R&D Process*

The topographical metaphor provides a way to visualize specific innovation paths within the larger setting of a knowledge context. With this dual perspective, we can more accurately assess the opportunities for developing information related to risk. Who are the key decision-makers in the production of knowledge about technologies? How and when can the law influence producers to generate data on side effects or to proceed with development that minimizes costs not yet fully identified?

1. *Research Incentives*

The topographical model highlights the distribution of information among communities of knowledge. Most knowledge of emerging technologies is shared in its earliest phases by a few individuals, generally located in firms specializing in particular kinds of research.[43] At first, this expertise is not available either to the tort system or to regulators. Instead, R&D researchers and the investors who employ them are closest to the knowledge horizon formed by new and changing technologies. In the earliest phases of a technical development, they must determine what further learning is possible and at what cost.

The commercial purpose of private R&D puts researchers under pressure to study the efficacy of a technology, rather than its HSE effects. Since lead time is a strong factor in the profitability of a new product, rivalry encourages efficacy research and discourages attention to product safety and side effects.[44] Particularly where research on side effects would take time and delay a product's introduction, there is a strong disincentive to study such effects.

The producers of the original technology also may fail to perceive its negative side effects because they are simply not looking for them. Unless the product poses an obvious risk, the innovator may inadequately research side effects. Research is often conducted on obvious side effects: for example, FDA requirements force pharmaceutical firms to conduct at least some research on health effects, because humans will certainly and clearly be exposed to their

43. *See* Merges & Nelson, *supra* note 33, at 868-77.

44. *See* George Eads & Peter Reuter, *Designing Safer Products: Corporate Responses to Product Liability Law and Regulation*, 7 J. PROD. LIAB. 263, 268 (1984). Eads and Reuter describe firms' responses to market and legal pressures to enhance safety in nine large and innovative manufacturing firms.

products. Furthermore, these companies must study the physical effects of their products on humans in order to develop efficacious drugs in the first place. In contrast, these circumstances generally do not exist in the development of technologies that produce pollution.

Other factors tend to discourage firms from producing data on HSE effects. The personal involvement of a firm's employees in its development effort creates incentives to ignore or suppress evidence of problems. Indeed, outright deception about and denial of product side effects is not uncommon.[45]

We tend to treat each case of deception or willful ignorance as anomalous, but both are predictable outcomes of the incentives that arise from the use of information, including scientific information, as a commercial resource. Innovators have financial and personal incentives to ignore, distort, and conceal unfavorable information about new products and processes.[46] Without some signal from the law that research on side effects has value, incentives to incorporate safety research are limited, and research on latent or uncertain effects will either be overlooked or postponed.

2. *Available Risk Information*

Although firms cannot specifically predict the HSE effects of emerging technologies, this should not excuse them from responsibility for considering health effects. The fact that a particular harm comes as a surprise when

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45. *See* George A. Akerlof & William T. Dickens, *The Economic Consequences of Cognitive Dissonance*, 72 AM. ECON. REV. 307, 316 (1982); Richard Peto, *Distorting the Epidemiology of Cancer: The Need for a More Balanced Overview*, 284 NATURE 297 (1980) ("So many examples of financially-motivated bias exist that the motives and work of industrial scientists and consultants are inevitably distrusted."); Sidney Shapiro, *Divorcing Profit Motivation from New Drug Research: A Consolidation of Proposals to Provide the FDA with Reliable Test Data*, 1978 DUKE L. J. 155, 161-68 (citing evidence that drug manufacturers' safety research is influenced by profit motive and that contractual relations between researchers and drug sponsors influence the quality of data).

Research by firms about their own products need not be actively falsified to fall short of a rigorous critique. This is a familiar theme in studies of regulation. *See* Peto, *supra*; Shapiro, *supra*, at 161-168; SISSELA BOK, SECRETS - ON THE ETHICS OF CONCEALMENT AND REVELATIONS 148-50 (1983). Incentives to consider health, safety and the environment are limited by other factors as well. Peter Cleary Yeager has noted empirical data suggesting that business culture places a low value on laws responding to social concerns (health, safety, labor rights) as opposed to those designed to safeguard the integrity of the marketplace. YEAGER, *supra* note 20, at 8-9.

46. *See* John Nordheimer, *Johnson & Johnson Sued Over Dismissal—Scientist Says He Was Pressured to Submit Misleading Test Data*, N.Y. TIMES, Nov. 9, 1994, at 50; Andrew Blum, *Reynolds Sues to Gag Ex-Staffers*, NAT'L L.J., Mar. 1, 1993, at 3, 43. The full record on suppression of evidence of the harmfulness of cigarettes has yet to be revealed. A useful history is presented by Rivka Widerman, *Tobacco Is a Dirty Weed: Have We Ever Liked It? A Look at Nineteenth Century Anti-Cigarette Legislation*, 38 LOY. L. REV. 387 (1992). Her discussions of recent scientific data, *id.* at 391, and of nineteenth century reasons for regulating cigarettes, *id.* at 398-402, are particularly relevant. The most recent controversy centers on the tobacco industry's possible suppression of data on the addictive nature of tobacco. *See Waxman Says Industry Suppressed Study Showing Addictive Nature of Nicotine*, 8 Toxics L. Rep. (BNA) 1248 (Apr. 6, 1994). Other instances of deception are cited in Ellen Relkin, *Some Implications of* Daubert *and Its Potential for Misuse: Misapplication to Environmental Tort Cases and Abuse of Rule 706(a) Court Appointed Experts*, 15 CARDOZO L. REV. 2255, 2260-61 (1994).

discovered may reflect the innovator's choices during innovation more than the inherent difficulties of discovering the side effect.

At least in the early stages of innovation, innovating firms are unquestionably in the best position to set the direction of the search for information.[47] If nothing more, firms know what information they lack and can anticipate what data should be generated. While researchers are not positioned to see everything, they can estimate the outcome of R&D efforts at various levels of input.[48] Data also suggest that most R&D money is spent on development.[49] The law, then, should send a signal early in the innovation process, before development funds are committed, that firms will be held accountable for the side effects of technologies.

Since firms already have information about the nature of their proposed products, the law's deterrence signal need be no more than a cue; it need not provide safety specifications for each product. Although as a matter of principle we might want to have the law provide firms with a legal standard that allows an exact measure of the acceptable social costs of each product, in practice this cannot be done. At the earliest stages of R&D, only those involved in the research process are in a position to identify potential social costs. In the case of technologies with latent effects, no one may be able to identify all costs, but in any event the producing firms have the best information. Firms are not left guessing. They do have knowledge about side effects and opportunities for developing more information.

Although firms have the best information about the risks of exposures, they may keep the information to themselves. The asbestos case is a good illustration. The asbestos industry has portrayed itself as surprised by the toxic effects of asbestos. But the catastrophe was not a surprise. Leaders of the asbestos industry may not have foreseen the full range of health effects from asbestos exposure, but serious and widespread harm was expected as early as the 1930s. Mesothelioma, the lung cancer associated with asbestos inhalation, was linked with exposure to insulation materials in the 1960s. However, asbestosis, an incapacitating and frequently deadly disease, had been known decades and even centuries earlier to result from the inhalation of asbestos. Asbestos firms knew about this disease. Basic health research on asbestos health effects was not out of reach or too expensive; in fact, the industry conducted such research and hid it.[50] Although the firms had the best

47. Even if the outcome of a search is not known, it may be possible to catalogue various possible outcomes. Nelson and Winter suggest that there is generally no single optimal research strategy, but that it is sometimes obvious that certain directions are likely to be productive. NELSON & WINTER, *supra* note 19, at 255-61.

48. *See* NELSON & WINTER, *supra* note 19, at 249.

49. *See* SCHERER, *supra* note 40, at 350; STONEMAN, TECHNOLOGY POLICY, *supra* note 27, at 110. Of course, these patterns will vary in different industries.

50. The asbestos industry repeatedly attempted to conceal the dangerous effects of asbestos and

information about the risks of asbestos exposure, they presented uncertainty and surprise as defenses to liability. The asbestos epidemic is simply an extreme example of a general phenomenon that both economics and common sense predict.

Awareness of potential human exposure to a product or process is a fork in the R&D path and should be recognized as a significant event. If the firm decides to research the potential safety problem further, it may identify specific unfavorable effects. The firm can then decide whether to abandon the project or to tailor it to minimize human exposure to the harm.[51] A firm can also take the chance that a court or an agency will strike the cost-benefit balance in its favor. It can also try to persuade the legislature that the product is worth the social costs associated with it and that the public should therefore compensate those whom the product damages. Congress has decided, for example, that childhood vaccines are such products. The law ought to recognize both the predictability of some effects from exposure and the variety of responses available to firms.

While technologically-based injuries generally do not come unannounced, there are, of course, true surprises. These surprises present difficult questions, but we need not design our deterrence mechanisms around them. During early learning phases, when we do not know the full effects of a product, the law should create incentives to research side effects and, for true surprises, the law should provide incentives for firms to identify risks at the first signs of dysfunction.

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to limit its liability. For instance, in 1933, eleven lawsuits brought against Johns-Manville were settled, conditioned on written assurance from the attorney that he would not participate in any new actions against the company. PAUL BRODEUR, OUTRAGEOUS MISCONDUCT 114 (1985). In 1934 Vandiver Brown, an attorney for Johns-Manville, persuaded a Metropolitan Life researcher to delete unfavorable references to the effects of asbestos from a study that was to be published by the United States Public Health Service. *Id.* at 114-15. In 1935, Brown and the president of Raybestos-Manhattan agreed to exclude any articles dealing with asbestosis from the industry trade journal *Asbestos*. *Id.* at 116-17. In 1947, the Industrial Hygiene Foundation, financed in part by both Johns-Manville and Raybestos-Manhattan, failed to publish a study showing that 20% of workers in two asbestos factories had developed asbestosis. *Id.* at 242. In 1949, the medical director of a subsidiary of Johns-Manville supported a policy of not informing employees of the results of X-rays showing they were developing asbestosis. *Id.* Furthermore, in the 1950s both companies deliberately attempted to suppress public knowledge concerning the relationship between asbestos and cancer. *Id.*

The asbestos industry was a leader in lobbying for a workers' compensation law, which proved beneficial to the industry. Asbestos industry lobbyists worked to convince lawmakers to amend existing statutes to include silicosis and asbestosis, to limit the amounts recoverable, and to restrict eligible claimants. *Id.* at 18. Johns-Manville's chief attorney noted that the enactment of occupational-disease legislation was "the strongest bulwark against future disaster for the industry." *Id.*

51. Although many products cannot be tailored in this way, many others can. For example, in many products asbestos fibers can be secured or encased to reduce the risks they pose. Product designs and workplace practices designed to minimize exposure would have prevented much of the asbestos catastrophe. This is not an argument for prohibiting all exposure to harmful substances, but for legal rules that encourage reductions in such exposure.

3. *The "Path-Dependency" of Technical Knowledge*

Innovation economics recognizes the temporal and spacial limitations within which technology emerges. The technical term for this rooted characteristic is path dependency. Path dependency in this context means that much R&D is incremental work on technologies already in use and that investment options are limited.

Path dependency also implies that investments may have long term channelling effects. The decision to develop technologies with widespread externalities may therefore have particularly significant social consequences. Moreover, a technology may become established and supported by influential economic interests before its detrimental side effects manifest themselves fully.[52] The R&D agenda may be narrowed and alternatives foregone, as firms delay adaptive measures necessary to address HSE side effects. Firms may direct their energies toward developing more sophisticated marketing techniques or lobbying for protection against environmental regulation or competition. Existing technologies not only frame the physical infrastructure of society, but also the way we understand it; the production of new knowledge is in part controlled by those who control incumbent technologies. Manipulation of information about a technology may inhibit the flexibility and resilience of the social system by reducing both the visibility of externalities and the system's ability to respond.[53]

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52. *See, e.g.*, Harvey Brooks, *The Typology of Surprises in Technology, Institutions, and Development*, *in* THE SUSTAINABLE DEVELOPMENT OF THE BIOSPHERE, *supra* note 17, at 329, 337-43. Brooks argues that in the early stages of a fundamental innovation, the structure of the industry using the new technology is fluid, with a high degree of diversity and experimentation. Many small firms explore different approaches and competition focuses on product performance, rather than price or even reliability. As one approach emerges as the dominant technology, its competitive position improves, but its accelerating success also reduces the number of competing technologies. As the technology and the industry mature and the scale of application increases, detrimental effects may begin to appear. "[N]ew problems resulting from the scale of application become important just when the broad type of R&D program that might have helped anticipate such problems has been phased out, because it is no longer necessary to the commercial success of the dominant technology." *Id.* at 336-37. Brooks cites the chemical industry as an example. Waste disposal and management of residuals were not perceived as barriers to further market expansion. Autos, pharmaceuticals, pesticides, electric power generation, commercial air transport, industrialized agriculture and many other areas appear to have similar patterns: successful innovation over an extended period becomes self-limiting, because of the failure to enlarge the innovation agenda sufficiently quickly, particularly in relation to externalities. *Id* at 337-38. *See also* Schwartz, *supra* note 2, at 330-33 (describing industry influence over regulatory agencies and placing this in the context of the tort reform debate).

53. In the worst case, unstable "technological monocultures" may result, with rigid, outdated or socially costly technologies insulated from scrutiny. C.S. Holling, drawing on work on monocultures in ecosystems, has suggested that resilience—"the ability of a system to maintain its structure and patterns of behavior in the face of disturbance"—is necessary to sustainable social systems. Crawford S. Holling, *The Resilience of Terrestrial Ecosystems: Local Surprise and Global Change*, *in* THE SUSTAINABLE DEVELOPMENT OF THE BIOSPHERE, *supra* note 17, at 296. *See also* Brooks, *supra* note 52, at 335-36. Brooks suggests that the problem of rigidity may be more severe for technological monocultures than for agricultural ones, since "organizations that have successfully commercialized the dominant technology acquire some power to influence the external environment or market in which they operate." *Id.* at 336.

Since investments in technology are not reversible as a practical matter,[54] path dependency and the secondary effects of investment decisions dictate that care must be taken in the initial selection of technologies and that warning signs of dysfunctions must be heeded. To the extent that mass technologies tend toward rigidity, the law should encourage flexibility and openness to change.[55] This means being receptive to signals of dysfunction and prepared to shift directions.[56] Tendencies to favor expectations and reliance may be more suitable to static and stable contexts.

C. *Law as a Learning Function*

The decision to preempt tort law in favor of agency regulation requires a great deal of faith in the rationality of the regulatory agency's agenda and in the agency's assessment and allocation of risks. Tort law's critics think that agencies are better learners than are courts, so much better that perhaps we ought to rely on agencies alone to deal with the side effects of technology. Critics of tort law see regulators not only as more competent than courts, but also as capable of a broad and sophisticated brokering of social costs and benefits that is infinitely preferable to the courts' naive tinkering. Analyses of the common law that focus on reducing barriers to transactions tend to reinforce the idea that regulation is preferable: regulations seem to be clearer and more consistent, reducing firms' uncertainty more effectively than does tort law. And the fact that HSE regulation is increasingly federal provides uniformity.

The assumptions underlying these conclusions bear examination. One assumption is that administrative agencies are able to prescribe optimal or efficient levels of risks. A second is that standards or other legal cues about appropriate levels of externalities can be made specific, so that firms can rely on them in making long term investments. According to these theorists,

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54. *See, e.g.*, Nathan Rosenberg, *Science and Technology in the Twentieth Century*, *in* TECHNOLOGY AND ENTERPRISE IN A HISTORICAL PERSPECTIVE 63, 78-82 (Giovanni Dosi et al. eds., 1992).

55. The importance of this social function is highlighted by Jerome Ravetz, who writes:

> In some ways our material culture is really rather brittle; our high technology and sophisticated economics depend quite critically on extraordinary levels of quality control in technology and on highly stable social institutions. Whether these could absorb a really massive environmental shock is open to question. The real resilience of our civilization may lie not so much in its developed hardware and institutions, as in its capacity for rapid adaptation and change.

Jerome R. Ravetz, *Usable Knowledge, Usable Ignorance: Incomplete Science with Policy Implications*, *in* THE SUSTAINABLE DEVELOPMENT OF THE BIOSPHERE, *supra* note 17, at 416.

56. Merges & Nelson, *supra* note 33, at 862-68 (discussing patent doctrine's capacity to adjust legal protections during the lifespan of a patent, and arguing that the doctrines of patent "equivalents" and "reverse equivalents" provide some flexibility for courts to determine that a patent technology has been rendered obsolete).

efficiency dictates that law be certain and specific so that investors can rely on it.[57]

The innovation literature does not support these assumptions. For instance, the usual description of firms and their behavior is incomplete. First, the importance of legal certainty is overestimated, as other factors are more important in firms' innovation decisions. Second, the argument for legal certainty calls, rather oddly, on agencies and courts to provide firms with information about how to make their products, when it is the firms that are experts and often the only ones aware of a product's potential to harm. The argument for certainty also tends to ignore firms' incentives to avoid researching the adverse side effects of their products and assumes that they generally resist the pressures to suppress or manipulate negative data.

The appealing image of a centrally located, expert agency, conducting a balanced and detailed quantitative analysis, overstates the practical abilities of regulatory agencies. Much of the criticism of tort law starts from the premise that the chief function of the law in risk management is to allocate the costs and benefits of risky technologies. The regulatory agency's definition of appropriate risk levels, based on a panoramic cost-benefit analysis, seems to carry out this function admirably.

But an examination of the dynamics of technical change and knowledge production reveals that cost-benefit allocation is not the only or even the primary function of the law in risk management. Risk allocation has a fundamental shortcoming: as a measure of technology, it comes late. When allocating risks, existing technologies frame our current choices, so the costs and benefits that are allocated are themselves determined by earlier choices to pursue one or another technical option. An efficient legal rule should influence the early development of new technologies and sustain incentives to reduce risks after they are introduced. We need a better understanding of the way deterrence operates in order to evaluate agencies' and courts' abilities in this respect.

The elements of deterrence are clearer when we look at knowledge production as a dynamic process. Since the cost of changing technologies increases as investment in a chosen technology mounts, the social value of risk information is greatest at the early stages of R&D. Legal rules should place

57. The claim that entrepreneurs have an efficiency-based entitlement to legal certainty seems overdrawn. Entrepreneurs are risk takers in the market. They are subject to uncertainty arising from the innovation process from market dynamics and from changing legal requirements. If a new technology develops or a current one is significantly improved, a patent may be worthless; if new regulatory standards are issued, an investment may be outdated. Definite standards may make immediate production decisions easier and this may in turn enhance short term efficiency and welfare. Yet if legal certainty locks society into a particular response to harmful technology, this hardly seems efficient. *See supra* part I.B.3.

a premium on early health and safety research;[58] some communication must alert firms to the problem and convince them that spending time and money on researching side effects is worthwhile. At the same time, rules should enhance information production and exchange as a technology is developing and in use. Testing and research requirements, burdens of proof, disclosure, and obligations are all essential elements of deterrence. There are therefore two basic deterrence functions: the early signal and parallel monitoring. Both entail information management tasks that vary from context to context and at different times. No single legal format can effectively address all of these concerns.

The literature on technical change also suggests that legal standards should be simple and firm. In many contexts, the danger that a deterrence signal will be ignored is greater than the danger that it will discourage investment. The deterrence signal works against strong incentives and opportunities to ignore HSE side effects. The law must communicate to firms that their work will be independently evaluated for its effects on safety and health and that there is a system which stands ready to perform this evaluation and impose the costs it identifies.[59]

Of course, we cannot measure precisely the effects of maintaining a strong liability system.[60] Few economists would undertake to quantify patent law's benefits to society,[61] yet that kind of proof is what some tort critics suggest is required to support the liability system. Tort law's warning exists in a market that exerts strong pressures to give short shrift to HSE research and to downplay negative signs that emerge in the R&D process.[62] Suggestions that tort law broadly discourages innovation are disturbing, but they generally

58. Ecological economists argue that we need to shift the general burden of proof of suitability onto new technologies. This position reflects not the demand orientation of standard market models, but the systems analysis of ecological economics. In this view, the ex post treatment of the market's choice of technologies, accepting its right to form the framework of evaluation, is mistaken.

59. *See infra* part III.

60. Measurement on such a grand scale may not be possible. *See* Michael J. Saks, *Do We Really Know Anything About the Behavior of the Tort Litigation System—And Why Not?*, 140 U. PA. L. REV. 1147, 1154-56 (1992). Saks points out that work on tort deterrence is overwhelmingly theoretical because of the difficulty of evaluating deterrent effects, and demonstrates that the data needed to measure tort's compensation role is not being generated. *Id.*

61. *See* George L. Priest, *What Economists Can Tell Lawyers About Intellectual Property: Comment on Cheung*, 8 RES. L. & ECON. 19 (1986).

62. When no one knows the truth of a necessary fact, as when a court is asked to make a complex causal connection based on new data, then the issue is how the law should react to uncertainty. Conservatism in science means being cautious in declaring a causal connection. Conservatism in health and safety law may sometimes mean the opposite. The burden of proof of such a connection in science may be a great deal higher than it is in the law, because courts are gleaning risk indicators from science and sending signals to the R&D process. *See infra* part II.C.

have not been supported by data.[63] The level of innovation is influenced by many social factors, and innovation is increasing.[64]

Moreover, a strong version of tort law is consistent with intellectual property law's approach to the task of stimulating innovation. Tort law's critics argue that the liability system dampens innovation incentives; they treat tort law as compromising patent law's reward. Tort law's cautionary note does, in fact, accompany patent law's offer of a reward. Patent law issues a general invitation to entrepreneurs to produce useful new technologies,[65] but if a product is not useful, presumably no one will buy it, and patent law does not concern itself with products that are both useful and harmful. Those products are tort law's concern. The law should reduce incentives that lead producers to ignore social costs.[66]

The debate over preemption has tended to focus on the shortcomings of tort law and has treated liability as conflicting with regulation. The next section examines the supposed defects of tort law and compares the liability system and regulation in light of the warning and monitoring functions identified here.

II. Courts and Agencies as Monitors of Technical Change

The liability system is commonly described as incompetent, as though judges and juries are patently unable to handle technical subject matter. Refinements of this criticism include the arguments that courts are not positioned to assess social needs accurately; that tort doctrine exacerbates this disability, because common law adjudication resists statistical and other systemic modes of analysis; that the coverage of the tort system is spotty and arbitrary, as it depends upon private individuals to bring suit and prove their cases; that courts are confined to ex post consideration of problems, so they cannot prevent harm, only adjust losses; and that common law signals to the market are weak and inconsistent, lacking the uniformity and the promise of enforcement that characterize regulation. The thrust of these complaints is that courts using tort law cannot gather, interpret, or communicate necessary information about technology, while agencies' expertise and centralization allow them to understand and manage technology.

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63. *See, e.g.*, PETER REUTER, THE ECONOMIC CONSEQUENCES OF EXPANDED CORPORATE LIABILITY: AN EXPLORATORY STUDY v-viii, 36-48 (1988).

64. *See, e.g.*, THE POSITIVE SUM STRATEGY (Ralph Landau & Nathan Rosenberg eds., 1986).

65. Patent law's nominal requirement that an invention be useful is almost never invoked to bar the grant of a patent. *See* Edmund W. Kitch, *Graham v. John Deere Co.: New Standards for Patents*, 1966 SUP. CT. REV. 293 (1966).

66. Tort law "draws a bottom line" of behavior by insisting on "at least a moderate level of due care" to discourage "those who would create especially high risks from engaging in activities." SHAVELL, ECONOMIC ANALYSIS, *supra* note 3, at 75-77.

If monitoring and guiding the process of technological development is part of the law's project, then it is important to consider the courts' and agencies' specific capacities to learn and communicate. Simple invocation of agency expertise is not enough. This Part highlights some abilities of courts making tort law and compares them to regulatory agencies' abilities. The discussion suggests that the regulatory and common law formats are both limited by information constraints, but that tort law's method offers some advantages. Indeed, if we look at the law as a learning function, some of the idiosyncrasies of tort law that are most criticized may actually be systemic advantages. Tort law or something like it is a necessary response to technology.

A. *Competence and Expertise*

Courts are commonly described as if they do not have expert resources or, worse, simply cannot understand technical material. This criticism tends to ignore the variety of information problems that face both courts and agencies. Although different kinds of information are available and useful in both the liability and regulatory systems,[67] tort law's critics are primarily concerned with the institutional ability to gather and process expert knowledge. They assume, perhaps, that shaping technology always requires complex and costly information, or that if complex problems can be solved, simpler ones will be resolved automatically. This is not always the case. Simple information developed early may prevent the need for a complex treatment later. Moreover, local knowledge may be necessary for expert deliberation.[68]

Agencies do not have a monopoly on expert knowledge. Neither courts nor agencies possess expertise when technologies are new or changing. At early stages of innovation, only researchers involved in R&D have this

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67. Steven Shavell distinguishes among three relevant types of knowledge: particular knowledge of the circumstances of the activity, expert knowledge, and common knowledge. In evaluating deterrence mechanisms, Shavell considers the accessibility and cost of each type of information. As a general rule, Shavell suggests that private parties will enjoy an inherent advantage with access to local knowledge, since they are the ones who engage in the activity and derive the benefits from it. Shavell, *Liability for Harm*, *supra* note 3, at 357, 359. Where local knowledge is key, he suggests that courts generally have an advantage over regulators, since they have the evidence presented by the litigating parties. Where information about risk requires effort or expertise to develop, regulators have the advantage, if they commit resources to the task. They may still have difficulty distributing the information, however. *Id.* at 360.

68. Shavell is no doubt right that much regulation can be justified by common knowledge or non-expert information, though expert analyses increasingly are required as part of the regulatory process. Shavell, *Liability for Harm*, *supra* note 3, at 359. Different deterrence decisions require different levels of information. It is inefficient to standardize risk assessment so as to require the same specifics for all decisions. *See* Mary L. Lyndon, *Risk Assessment and Legitimacy, an Introduction to the Symposium*, 14 COLUM. J. ENVTL. L. (1989) 289, 303; Bernard D. Goldstein, *Risk Assessment and the Interface Between Science and Law*, 14 COLUM. J. ENVTL. L. 343 (1989); *see also* Adam M. Finkel, *Is Risk Assessment Really Too Conservative?: Revising The Revisionists*, 14 COLUM. J. ENVTL. L. 427 (1989) (discussing factors which make each risk assessment unique and disadvantages of standardizing QRA components).

knowledge. Once it is disseminated, both agencies and courts usually rely on the work of outside specialists and, in fact, both institutions often use the same experts. Expert data and methods are costly in both contexts,[69] and information may bring no greater certainty in one setting than in the other.

Courts may treat problems more thoroughly than can agencies. The case framework allows a court to explore a specific question in depth, without substantially committing public funds. A tort case is a layered process in which technical and scientific data and experts—often the same resources used by regulating agencies—are brought to bear on a problem.

Some scholars question the adjudication process itself. These critics argue that the common law is not "scientific," that courts cannot collect samples and make decisions in a scientific way.[70] Of course, courts are not "doing science," though they must periodically evaluate scientific evidence. Common law courts are learning to cope with the quantification inherent in statistical evidence necessary to prove some causal connection.[71] Furthermore, much of science consists of case studies of physical symptoms in occupational and other contexts. Tort cases build upon these.

Regulation may also be seen as more impartial than court decisions. However, it is a mistake to see agencies as operating in isolation from lay society. On the contrary, the political context in which agencies work makes them in some respects less free to be true to science than are courts. Similarly, to some critics the problem with the court system is not that judges are incompetent but that the court system relies on lay juries. However, public participation and legitimacy are necessary in the regulatory context.[72] At least in its current configuration, regulation is fundamentally limited by its political setting.

The question of whether courts are incompetent to manage scientific, economic, and statistical information is in some sense moot, since many categories of cases now raise technical questions. We cannot simply delegate all so-called law and science problems to non-judicial forums without abolishing a great deal of jurisprudence, including much of administrative law's judicial review of agency action. The Supreme Court's decision in *Daubert v. Merrell Dow* points us in a more positive, though demanding, direction.[73]

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69. *See* Lyndon, *Information Economics*, *supra* note 18; John S. Applegate, *The Perils of Unreasonable Risk*, 91 COLUM. L. REV. 261 (1991) (discussing costs of agency approach).

70. *See, e.g.*, Viscusi, *Diminished Role*, *supra* note 1, at 74 ("[T]he individual case approach is not well suited to broad scientific inquiry.").

71. *See* Steve Gold, *Causation in Toxic Torts: Burdens of Proof, Standards of Persuasion, and Statistical Evidence*, 96 YALE L.J. 376 (1986); Michael Green, *Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Lesson of Agent Orange and the Bendectin Litigation*, 86 NW. U. L. REV. 643 (1992).

72. *See, e.g.*, Daniel J. Fiorini, *Environmental Risk and Democratic Process: A Critical Review*, 14 COLUM. J. ENVTL. L. 501 (1989).

73. Daubert v. Merrell Dow Pharmaceuticals, 113 S. Ct. 2786 (1993). Courts apparently are

The focus should be on making technical assistance more available to the courts.[74]

B. *Legal Process as a Learning Format*

Liability and regulation present distinct formats which set up different patterns for managing information problems. Both types of law use different techniques to analyze and manage information. Regulation in particular takes a wide variety of forms. In order to compare regulation with the common law, this section will focus on one of regulation's more prominent methods, Quantitative Risk Assessment (QRA).

QRA is frequently used to identify and measure the health impacts of regulatory proposals.[75] In 1983, the National Research Council (NRC) issued guidelines designed to standardize risk assessment methods for use in assessing the risks from exposure to chemicals. While the NRC's general format has remained constant, the specific ways in which the QRA process is carried out vary from agency to agency.

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taking seriously the screening function that *Daubert* articulated. *See* Jonathan M. Hoffman, *Expert Testimony Since* Daubert: *A Major Shift*, 9 Toxics L. Rep. (BNA) 252 (1994). For discussion of the issues raised by judicial screening of scientific evidence, see Relkin, *supra* note 46, and Peter A. Bell, *Strict Screening of Scientific Evidence: A Bad Idea Whose Time Has Come*, 6 Toxics L. Rep. (BNA) 1014 (Jan. 22, 1992), 1047 (Jan. 29, 1992). Much of the recent debate over the use of scientific evidence in the courts has been framed by one factual pattern which recurs periodically in the toxic torts context, that is, the situation in which a substantial amount of epidemiological data on an exposure reveals no human health effects, while other toxicological methods suggest high toxicity and may support links to particular diseases. Both Agent Orange and Bendectin fit this pattern. However, it would be a mistake to use this model as the standard for all cases, since this juxtaposition of the evidence is not the rule and, in any event, both types of data are generally unavailable; both are expensive and time consuming to produce. Indeed, epidemiology, the current favorite type of science in toxics cases, is necessarily ex post facto and can establish causal connections only after widespread and human exposure to a substance. *See* Lyndon, *Information Economics*, *supra* note 18, at 1799-1810; Relkin, *supra* note 46, at 2258-60.

74. *See, e.g.*, CARNEGIE COMM'N, SCIENCE AND TECHNOLOGY IN JUDICIAL DECISION MAKING: CREATING OPPORTUNITIES AND MEETING CHALLENGES (1993). *See* discussion *infra* part III.

75. For general discussions of risk assessment, see CARNEGIE COMM'N, RISK AND THE ENVIRONMENT: IMPROVING REGULATORY DECISION MAKING (1993); NATIONAL RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS (1983); [hereinafter NATIONAL RESEARCH COUNCIL, RISK ASSESSMENT]; NATIONAL RESEARCH COUNCIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT (1994) [hereinafter NATIONAL RESEARCH COUNCIL, SCIENCE AND JUDGMENT]; Symposium: *Risk Assessment in Environmental Law*, 14 COLUM. J. ENVTL. L. (1989); Michael S. Baram, *Use of Comparative Risk Methods in Regulatory and Common Law*, 13 COLUM. J. ENVTL. L. 1 (1987); Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 YALE J. ON REG. 89 (1988); *see also* MARY DOUGLAS & AARON WILDAVSKY, RISK AND CULTURE (1982); CHARLES PERROW, NORMAL ACCIDENTS—LIVING WITH HIGH RISK TECHNOLOGIES (1984).

QRA developed rapidly in the late 1970s and the 1980s. Its emergence in chemical regulation seems to be a classic case of paradigm formation as described by Thomas Kuhn. With risk as the organizing concept and risk assessment as the format for elaboration, risk analysis provides an "implicit body of intertwined theoretical and methodological belief that permits selection, evaluation, and criticism" in a field that was previously awash in facts of apparently equivalent importance. THOMAS S. KUHN, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS 15-17 (1962).

The NRC articulated a distinction between risk assessment and risk management and then identified four separate steps or phases in risk assessment. These are hazard identification, the identification of a causal link between exposure to a particular chemical and a particular health effect; dose-response assessment, the determination of a relation between the magnitude of exposure and the probability of occurrence of the health effect; exposure assessment, an estimate of the extent of human exposure to the chemical; and risk characterization, a description of the nature and magnitude of the risk arrived at through these first three steps. The level of uncertainty about the risk characterization is part of the final risk number.[76]

The requirement that uncertainty be identified is more than a formality. The QRA process gathers, evaluates and amalgamates data and analyses which are gleaned from different disciplines and, even within the same discipline, often rely on differing methodologies. The NRC notes that missing or ambiguous information and gaps in current scientific theory require the risk assessor to make numerous inferential bridges. These often entail a choice among several scientifically plausible options. The report designated the points at which such inference choices must be made as "components" and then listed fifty-one components which may be found in a carcinogenicity risk assessment.[77]

Given the uncertainty of this process, QRA has been a controversial tool. For instance, some believe that it will eventually be refined to become a general measurement method useful in risk-related contexts ranging from liability to regulatory standard-setting.[78] However, others argue that because of its generality and the variability of the quality of information QRA relies upon, it is primarily useful to gauge the broad costs of different types of polluting activities and controls.[79] However, it is not usually produced in a way which facilitates comparisons between rival technologies or control strategies.[80]

Another controversy has centered around whether risk assessment—the factual side—and risk management—the value or policy side—can and should be separated. The NRC continues to view the two as separable and to maintain that they must be handled as two distinct policy functions. Others argue that the emphasis on separating them tends to obscure the many value-laden choices

76. NATIONAL RESEARCH COUNCIL, RISK ASSESSMENT, *supra* note 75, at 3, 33-37.

77. *Id.* at 28-33.

78. *See* Elizabeth L. Anderson, *Scientific Developments in Risk Assessment: Legal Implications*, 14 COLUM. J. ENVTL. L. 411, 425 (1989); Dennis J. Paustenbach, *Health Risk Assessment: Opportunities and Pitfalls*, 14 COLUM. J. ENVTL. L. 379, 409-10 (1989).

79. Goldstein, *supra* note 68, at 351.

80. Barry Commoner, *The Hazards of Risk Assessment*, 14 COLUM. J. ENVTL. L. 365, 366-67 (1989).

on the factual side and to increase the dominance and mystique of science as a neutral arbiter in social choices that are finally political questions.[81]

QRA elaborates on the basic techniques of decision-making under conditions of uncertainty, by converting all expected harms into one quantity to facilitate comparison and selection. For example, a typical environmental QRA might calculate expected human exposure to a particular chemical and apply scientific judgments about the cancer deaths likely to result from different levels of exposure. The final product, the risk characterization, is expressed as either a numerical estimate of individual cancer risk or as the range of cancer fatalities expected to result in the population. The agency then computes the social costs of the activity, expressing the value of the fatalities in monetary terms. A QRA thus purports to specifically describe the significant risks associated with an activity and to allow society to manage resources according to a visible ledger of risks and benefits. This conception of optimal welfare as a rational allocation of harms, with its clear vision of efficient safety, is a central reference point for much of current policy analysis.

Tort law, unlike QRA, does not try to standardize or measure. Its goals and achievements are impossible to assess with precision; its subject is the unexpected accident. Tort law may appear unable to assist in planning and management, while QRA and the resulting regulation, on the other hand, may seem more useful because they are scientific.[82] Yet if we consider the value of information in different settings, this description begins to appear simplistic.

QRA and cost-benefit analysis, when used to rank programmatic priorities, are powerful organizational assets. When we are choosing how to allocate public money for enforcement or how strictly to control the costs of different industries, QRA makes it possible to perform a comparison of options across different categories of programs. When it is offered to support specific standard-setting decisions, however, its value must be judged differently, especially if the standard is to preempt all other legal devices.[83]

The structure of regulation's tools and their ability to synthesize data entails certain weaknesses. Each choice to simplify the decision process may also be a choice to ignore some cues. For example, most QRAs focus on

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81. *See* Kristin S. Shrader-Frechette, *Reductionist Approaches to Risk*, *in* ACCEPTABLE EVIDENCE 233-38 (Deborah G. Mayo & Rachelle D. Hollander eds., 1990); KRISTIN S. SHRADER-FRECHETTE, RISK AND RATIONALITY 7-9 (1991) (citing authors arguing that scientific objectivity does not exist and that risk evaluation is "wholly relative").

82. *See* George P. Fletcher, *Fairness and Utility in Tort Theory*, 85 HARV. L. REV. 537 (1972) (describing the appeal of the scientific style and its promise of precision and rationality); *see also* Nancy A. Weston, *The Metaphysics of Modern Tort Theory*, 28 VAL. U. L. REV. 919 (1994) (analyzing tort theory in terms of control and will); Peter A. Bell, *Analyzing Tort Law: The Flawed Promise of Neocontract*, 74 MINN. L. REV. 1177, 1203-5, 1221-27 (1990) (noting the "coolness" of "predetermined law" and contrasting this with tort law).

83. *See* CARNEGIE COMM'N, *supra* note 75, at 73-95 (discussing appropriate use of QRA in setting priorities).

cancer effects, but this is a narrow indicator which is inexact as a measure of broad effects. Collapsing the whole range of human health and environmental effects into one measure, such as a complex disease or group of symptoms, is not particularly useful for a monitoring system.[84] Also, since a large amount of information is required to determine cancer risk, and it is costly to establish individual cancer links with a fair degree of consensus, cancer is a measure that can only be applied well after it has been caused.

The quantification process inherent in cost-benefit analyses and QRAs tends to obscure differences in the quality of information on which they are based.[85] The format implies that there is only one accurate cost-benefit balance that should be adopted as a basis of policy. This assumption, in turn, supports the idea that sending two different legal messages to a firm will encourage contradictory results. But the actual process the law is trying to affect is more complex. Regulation and tort law may both counsel the same course of action, depending upon the options available on the firm's particular terrain.

While the common law approach is clearly limited in some respects, if the law's role encompasses deterrence and learning, rather than merely cost-benefit allocation, tort law has some clear advantages.

The common law's treatment is contextual. The case format is event and transaction-based and yields specific information about the context of an injury, which may hold key data. A close look at the context of an injury may provide clues about opportunities for reducing risks and learning about surprises.[86] The law should have access to this context.

Courts provide a forum for consideration of specific defects or harms identified by the plaintiff on an ad hoc basis. This format might be less information-intensive and less costly than an agency's process, yet may be effective in deterring costly harms. A tort case may not give a complete answer gabout the risks posed by a broad social development, but it may contain important data about emerging trends.[87]

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84. Carcinogenesis is typically difficult to establish, and the burden of proof is usually on the regulator, at least de facto. Many risks that cannot be proven to be significant by this method may still have large environmental effects. *See* Finkel, *supra* note 68.

85. These methods of decision-making handle complex information problems by estimating future developments and costs, discounting future values, and balancing costs and health risks as they appear at the time of the analysis. A National Research Council report has urged EPA to devote additional effort to describing uncertainty more fully in order to increase the value and flexibility of QRA as a decision tool and as a basis for later action. NATIONAL RESEARCH COUNCIL, SCIENCE AND JUDGMENT, *supra* note 75.

86. *See* Peter Timmerman, *Mythology and Surprise in the Sustainable Development of the Biosphere*, *in* THE SUSTAINABLE DEVELOPMENT OF THE BIOSPHERE, *supra* note 17, at 435; *see also* Garry D. Brewer, *Methods for Synthesis: Policy Exercises*, *in* THE SUSTAINABLE DEVELOPMENT OF THE BIOSPHERE, *supra* note 17, at 455.

87. The first asbestos cases did not indicate the scope of the problem, but the asbestos industry could piece together the complete picture. There is substantial evidence that this problem was in fact

The case method may pick up early, although partial, information. Firms will understand the significance of risk cues. A court considering a technology's impact is working temporarily within the technical culture of the industry. The court does not need to understand the technical culture fully in order to make a decision that gives an appropriate cue.

The case method allows gradual consideration of problems as knowledge develops. The common law courts are not obsessive; they do not need to be complete and their attention span is long. They can tell part of the story and let the rest emerge later. A common law court's repetitive consideration of similar events allows the tort system to develop an assessment over time, examining facts which may not have appeared in earlier cases.[88] In contrast, QRA's attention span is short.[89]

Many criticisms of the case method are aimed at tort doctrine itself.[90] Compared to an agency standard, tort law appears fragmented and unfocused. Its reach is so broad that a plaintiff can bring virtually any injury before a court. With this reach, the tort system acts as a kind of dragnet for injuries. But a monitor that stands open to receiving information about a broad range of harms can be a virtue. In contrast to the tort system's open weave, regulation focuses upon the agency agenda. This approach is limited; early warnings are not the priority, and the regulatory format is not particularly receptive to them. Cost-benefit analysis further concentrates the regulatory agenda, as it quantifies unknowns in order to fit them into the known framework.

Not only is the common law's reach broader, but it applies social principles to resolving problems. It relates the event before the court to the wider system of law. While experts are personally concerned with the questions posed by their discipline, lay and legal participants in court pose broader questions which establish a framework for selecting expert knowledge. Diversity of input and feedback and the participation of various kinds of

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understood. Early warnings from individual cases, even if incomplete, may be cost-effective clues to broader understanding. *See* BRODEUR, *supra* note 50.

88. Rose-Ackerman argues that where injuries are similar, regulation is better, since it is wasteful for courts to take information on many similar cases. This may be true, but class actions, collateral estoppel, and settlement should reduce repetitive litigation of identical problems, especially in mass tort contexts. Two thoughtful discussions of preclusion issues are Michael D. Green, *The Inability of Offensive Collateral Estoppel to Fulfill Its Promise: An Examination of Estoppel in Asbestos Litigation*, 70 IOWA L. REV. 141 (1984), and Mitchell A. Lowenthal & Howard M. Erickson, *Modern Mass Tort Litigation, Prior Action Depositions and Practice-Sensitive Procedure*, 63 FORDHAM L. REV. (forthcoming Mar. 1995).

89. A QRA usually is not repeated or updated, in part because it is so unwieldy and expensive. *See* NATIONAL RESEARCH COUNCIL, SCIENCE AND JUDGMENT, *supra* note 75, at E-13 to E-14; Joseph H. Highland, *Perceived Problems in the Applications of Risk Assessment Analysis*, 14 COLUM. J. ENVTL. L. 593 (1989).

90. Calabresi suggests that the common law method doctrinal framework leads courts to focus on the idiosyncrasies of the particular case, which is likely to distract from general patterns which should be controlled. GUIDO CALABRESI, THE COST OF ACCIDENTS 255-59 (1970).

experts and nonexperts are structural advantages for the system as a whole.[91] For instance, courts may legitimately be concerned with firms' failure to disclose data. Fraud and suppression of data may have broader ramifications than the proof in an individual case; they may restrict the development of scientific knowledge about causal links.[92] Instead of simply hearing the existing scientific evidence, the common law format allows courts to consider and weigh factors that affect the development of science. Tort law is also free to put in question the social value of a particular technology. The imperative of progress is subject to other considerations, such as the effect a technology will have on the quality of life.

Experts do not control the information that courts consider, as they do in the case of agencies.[93] There are limits on who can invoke the courts' jurisdiction, but they are defined in general terms and there is not, at least in principle, a monopoly on the use of the system. In contrast, QRA is run by experts and is therefore arcane and virtually inaccessible as a practical matter to those outside the policymaking process.

Recent proposals to refine and reform QRA in fact incorporate some of the attributes of tort law. The National Research Council has recently recommended greater use of narrative evaluation of each particular QRA's strengths and weaknesses and has stressed that the Environmental Protection Agency (EPA) should develop an iterative approach to risk assessment, providing for different levels of intensity in investigating and testing of chemicals. This approach would identify further research needs and provide incentives for regulated parties to undertake research, without the need for

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91. Ravetz, *supra* note 55, at 427-48 (describing taxonomy of participants in policy process including "public interest groups").

92. *See generally* Lyndon, *Secrecy and Innovation*, *supra* note 18.

93. *See* CHARLES M. HAAR & DANIEL W. FESSLER, THE WRONG SIDE OF THE TRACKS (1986) (evaluating this facet of the common law as a factor in the development of the legal value of social equality). Harvey Brooks suggests that we need to cultivate deliberately the variety of our responses to technology, including in social innovation. He argues that society should accept and support "policy entrepreneurs" such as Rachel Carson, Ralph Nader, Jeremy Rifkin, and public interest groups:

> Such efforts might be better judged not on the accuracy or reliability of the information they disseminate or the views they espouse, but on their indirect contribution to the more general broadening of the response pools of institutions and of societies. Disruptive, and even "irresponsible" as such activities may appear in the short run to some critics, they can be regarded as a form of [behavioral insurance] for the society, which may contribute to its future adaptability. The important point is that the notion of variability in the societal response pool is inseparable from the existence of error. One cannot experiment and explore without making errors.

Brooks, *supra* note 52, at 342-43. One commentator argues that Brooks is describing a picture of a societal learning system. In order to be effective, such a system, "in spite of its massive accumulation of experience, has somehow to remain sufficiently self-critical to jettison or to reorganize its knowledge, its perceptions, its in-built assumptions, whenever—or preferably, just before—their obsolescence is made manifest. It has to learn, in the context of technological development, the difference between full speed ahead, and optimal speed, right direction." (footnote omitted) Cantley, *supra* note 17, at 349-50.

panoramic evaluations of each chemical.[94] The Council has also stressed the importance of more explicit identification of the many uncertainties in QRA, precisely because the ultimate decision maker is not an expert, but a manager with political accountability.

QRA is costly and it has limitations. As the centerpiece of health and safety regulation it has obvious strengths, but these do not substitute for all of tort law's contributions. In particular, tort law's ability to operate independently of the regulatory agenda and to consider individual cases make it a useful supplement to regulation.

C. *Communicating Deterrence Signals*

Tort law is also criticized for being unable to influence firms appropriately. One type of objection is based on the courts' temporal and spatial position with respect to technology. Critics argue that courts cannot assess and manage risks from their vantage point in the system.[95] Because tort law operates ex post, critics claim that it does not optimally prevent injury. A second complaint is that tort law's deterrence signal is incoherent because it is vague and inconsistent. On close examination, however, these criticisms are not compelling.

1. *Institutional Vantage Points*

If we think of the "knowledge topography" as a spatial arrangement, we can visualize differences in the ways the two legal formats organize available information. Regulation simplifies and centralizes data, but it may tend to obscure local complexities.[96] The courts' use of the common law and case method places the liability system closer to local knowledge, as it is open to different kinds of knowledge. This information may sometimes provide the key to risk control.

Village of Wilsonville v. SCA Services[97] is a classic illustration of the importance of local knowledge. There, the state environmental agency granted a permit to a waste disposal firm, based on the agency's examination of the firm's application and its own review of the situation. Later, the Village and its residents sued in nuisance, pointing out that the waste site was constructed over abandoned mine shafts, which substantially raised the likelihood of

94. *See* NATIONAL RESEARCH COUNCIL, SCIENCE AND JUDGMENT, *supra* note 75, at E-13 to E-14, 12-27.

95. *See* Huber, *Safety and the Second Best*, *supra* note 1, at 306-07.

96. *See* Finkel, *supra* note 68, at 432-35.

97. Village of Wilsonville v. SCA Servs., 426 N.E.2d. 824 (Ill. 1981).

subsidence in the terrain and consequent leakage of hazardous waste. The presence of the mine shafts was local lore and not part of the agency's record when it granted the permit.[98]

Some authors also suggest that tort law's temporal position is a disability. A rational deterrent should operate in advance of the harm, but critics argue that tort law's piecemeal and inconsistent adjudications dilute the effectiveness of tort standards as deterrents. Clearer standards could be formulated by a regulatory agency in advance of the harm, and these are more likely to be uniformly applied.[99] Neither of these claims for regulations is necessarily correct. The areas where ex ante controls would be most beneficial also are likely to be those in which such controls are most difficult to establish, precisely because of the slow unfolding of technical information.[100]

In fact, the temporal distinction between tort law and regulation is overdrawn. Neither regulation nor tort law has the advantage in this situation. Enforcement of regulatory standards is not automatic and often is handled unevenly. Tort law and regulation both perform ex post and ex ante. The key question is, what events should they precede and follow? For deterrence, we want the law to send a signal before R&D investment, particularly before substantial development. Specific regulations, however, cannot be written at least until R&D has begun and become public or is reported to the agency. Even the pre-marketing registration and safety requirements of the FDA are applied after products have been developed. Most regulation in other areas is based upon cost-benefit analysis conducted ex post development. Even incentive-based regulatory systems follow the development of information about side effects.[101] Although technologies must be evaluated after they have

98. *Id.* at 831-33.

99. The ex post nature of tort law is regularly cited and sometimes stressed as a shortcoming of tort law as a deterrent. Although it is generally acknowledged that tort law sends signals, the literature tends to view regulation as ex ante, tort law as ex post. Rose-Ackerman writes that agency rulemaking "affects behavior ex ante without waiting for harm to occur . . . ." and that "Support for the tort system persists even when the logic of efficient risk control demands ex ante regulation . . . ." Rose-Ackerman, *in* TORT LAW AND THE PUBLIC INTEREST, *supra* note 1, at 83, 86. Viscusi describes the market as ex ante and tort law as ex post; regulation may be either, but it is treated as ex ante. W. Kip Viscusi, *Diminished Role*, *supra* note 1, at 70 (1989).

100. Rose-Ackerman suggests that the areas where tort law should most clearly be preempted are, ironically, the areas in which judicial doctrine has been the most innovative—toxic torts, products liability, and medical malpractice—since these are areas where she suggests ex ante regulation enjoys distinct advantages. SUSAN ROSE-ACKERMAN, RETHINKING THE PROGRESSIVE AGENDA 121-22 (1992). Given full understanding of the effects of a product or practice, ex ante regulation may be better than liability, but often latent effects are not be easily identified and take time to be fully understood.

101. Viscusi argues that the market functions ex ante, but this also presumes the existence and availability of risk information. As Viscusi points out elsewhere, the market does not produce this data alone. Court proceedings generate studies to document claims. He suggests that government regulation is the most effective institution for generating new risk data, through funding its own research and requiring research in support of license applications; the government disseminates information and uses experts to make decisions based on scientific information. Viscusi, *Diminished Role*, *supra* note 1, at 74-76.

been developed, it is also desirable for the legal system to send a signal to researchers at the beginning of the process, so that whatever technologies emerge from R&D investments have already been screened to some extent.

Regulatory schemes do form expectations about what kinds of effects will be acceptable.[102] The FDA in particular has imposed a research pattern on the pharmaceutical industry. But in general there is considerable uncertainty in an agency's signal.[103] This uncertainty exists partly because regulation is affected by the same developing knowledge that affects tort law's reaction to a technology. To the extent an agency's QRA relies on the latest research on the carcinogenic effects of a substance, it can act no earlier than can a common law court.

The very generality of tort duties and the rule of stare decisis together send a message which can form ex ante expectations about the law's response to new products.[104] Since tort law stands ready to be applied to any provable injury, its signal is available at the early stages of research and development. The question, then, is whether the signal is an effective one.

2. *The Clarity of the Deterrence Signal*

Tort law's critics argue that unpredictable and inconsistent adjudications add risk to corporate decision-making and serve no purpose. They claim that the signals tort law sends to firms in the marketplace have little specific content or meaning and may distort economic relationships by affecting rivals differently.[105] Agencies' performance is considered better in this respect; regulatory signals are seen as consistent and uniform.[106]

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102. If an agency consistently produces good allocation decisions, this pattern sends appropriate signals to those who are preparing to enter the market, including investors in new technologies. Particularly if the agency's method of decision-making is replicable by firms, they should be able to predict government reactions to their products and plan accordingly. Of course, firms may invest in influencing agency decisions. Also, agencies do not now include compensation for damages in their cost-benefit analyses.

103. Command and control regulation does not occur until bad effects are identified and determined to be significant. Such regulation does not penalize firms for these effects, except that they may have to add to or replace capital investment. It is important to note, however, that firms receive favorable tax treatment on such investments and that regulators generally allow time for firms to adjust to new standards. *See* Nicholas A. Ashford et al., *Using Regulation to Change the Market for Innovation*, 9 HARV. ENVTL. L. REV. 419 (1985).

104. *See* Ruckelshaus v. Monsanto, 467 U.S. 986, 1010 (1984).

105. ROSE-ACKERMAN, *supra* note 100, at 122. Rose-Ackerman notes that inconsistent enforcement of statutes can do the same thing. *Id.*

106. The economic value of uniform requirements is not settled, however. Economic criticism of command and control regulation suggests that it is inefficient to require all firms to take the same precautions. SHAVELL, ECONOMIC ANALYSIS, *supra* note 3, at 74-77. One commentator has written, "Savings in social costs [from nonuniform regulations] will accrue if the efficient risk reduction strategies are highly firm-specific and hence could not have been effectively prescribed by regulators." Viscusi, *Diminished Role*, *supra* note 1, at 79 n.77. It is also argued that some parties ought to exceed the regulatory standards, because they create a higher-than-average risk of harm, could take greater precautions more easily than most, or can take precautions not addressed by the regulation. According

While similar defendants may not receive the same verdict in different tort adjudications, producers as a group do receive the message that negative side effects will be attributed to their product. It is likely that all firms creating similar hazards from the same type of activity will be sued once one is made to pay for proven effects. Much of the uncertainty of tort law's signal stems from difficulties plaintiffs in general face in using the tort system. The current likelihood that any injury will be adjudicated at all is small. This probably results from limited access to the courts and the high costs of litigation, rather than from the nature of liability itself.[107] The tort system could be strengthened to make its signal more consistent.

On one level, the criticism of tort law's signal faults judicial opinions because they fail to provide specific guidance to producers as to how they should behave. After a tort trial, for example, pesticide manufacturers will have learned neither how to produce safer pesticides nor the level of safety they must achieve in the future. This does not mean, however, that they have received no useful information. Tort law's signal simply tells producers they may have to pay for failing to address the safety dimensions of their activities. Its binary message—liability or no liability—establishes a general standard for R&D: the product must have no extremely harmful side effects; it must not injure a large number of people. The message will not be full of specifics about a particular product because that type of expertise is local to the business. The liability rule operates as a cue to legal experts within the firm; the location of specific information.[108]

Tort law's message to producers investing in R&D is simply that researchers should examine side effects.[109] Any early signal has to be a general one, as only a very small group—the R&D team and investors—even knows about the specifics of a new development. Time and space constraints

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to this view, liability has a valuable role. Regulators may be unable to tell atypical firms apart, but liability will induce such firms to take valuable precautions beyond those required by the agency. Shavell, *Liability for Harm*, *supra* note 3, at 365-66. Thus, rules that ignore local knowledge and local conditions of production may lead to inefficient outcomes.

But tort law's critics tend to ask a different and larger question: Does the overall legal system efficiently allocate costs and benefits? In this view, tort decisions can undermine a system-wide accounting made by an expert administrative agency from its central vantage point. This approach seems to go beyond Shavell's analysis, since it demands that we actually measure the overall efficiency of legal controls. The agency is the institution that is deputized to make this overarching measurement of costs and benefits.

107. *See* Saks, *supra* note 60, at 1166-89.

108. The common law provides a test to be applied by local specialists in the technology and in the law: the design engineer and the counsel to a firm. The difference between strict liability and negligence, for example, may not be very important to business decision makers. The important question is how the law is perceived by corporate counsel and how it is communicated to clients. Corporate counsels' incentives are to paint worst-case, maximum legal uncertainty. *See* Lyndon, *Information Economics*, *supra* note 18.

109. Eads & Reuter, *supra* note 44, at 290. ("Because the linkage between a good design and a firm's liability exposure remains tenuous, the signal says only: 'Be careful, or you will be sued.' Unfortunately it does not say *how* to be careful, or, more important, *how careful* to be.").

dictate, in some cases, that science cannot provide a clear content for the signal. Firms are left with a difficult task, but it should not be overdrawn.

How much should researchers invest in looking for side effects? There are limits to a firm's ability to research the health and safety effects of its products and processes. R&D must be cost-effective.[110] Recognizing these limits more clearly should lead us to consider other options, such as cooperative or subsidized third-party research efforts.[111] These approaches are considered in Section III.

Could we refine QRA and risk communication so that agencies could send a more useful signal than does tort liability? Agencies could settle on a risk level that would trigger controls, such as a rule that no more than one or ten or one hundred cancers per million persons are acceptable. Theoretically, investors could then do their own QRAs and develop products to fit the allowed risk levels. But the science involved in arriving at a risk estimate varies from case to case and may remain undeveloped for a period of time. A firm may estimate the risks for a new technology and then find itself litigating the adequacy of its risk assessments. This hardly seems better than the common law's mandate to "make it pretty safe."

The current regulatory focus on carcinogenesis leads to overvaluation of information about cancer. Exposures may cause a number of acute and chronic diseases, with cancer being the last to appear. If we focus on cancer in spite of possible earlier signs of harmful respiratory or neurological effects, we may miss signals to stop exposure earlier, before the genesis of any cancer. The tort system directs R&D participants to look for risks and costs in general. It does not limit their search to particular effects identified by regulators.

The assumption that tort law and regulation pose awkward and conflicting alternatives for industries is also simplistic. Firms are elaborating alternatives which are formed by many factors. The legal messages sent by regulation and tort law need not be inconsistent and may, in fact, reinforce each other. Any inconsistencies arise from a later signal which requires a change in direction and is costly to accommodate.[112] Normally tort law should be the earlier signal. If firms believe the tort system will make them pay for costs, agencies

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110. *See* Merges & Nelson, *supra* note 33; *see also* Alan Schwartz, *Product Liability, Corporate Structure and Bankruptcy: Toxic Substances and the Remote Risk Relationship*, 14 J. LEGAL STUD. 689 (1985).

111. *See* Lyndon, *Information Economics*, *supra* note 18, at 1841-55.

112. We have few actual cases in which to study the relative effectiveness of tort and regulatory signals, since both tort law and HSE regulation are relatively recent developments and both have been applied primarily to existing technologies, where considerable investment has already occurred. *See* Kahn, *supra* note 1, at 1168-71 (discussing the history of automobile safety mandates in regulation and the common law).

It has been argued, however, that products liability generally has a greater effect on product design decision than any other incentive for safety—regulation is more influential only in a few highly regulated industries, such as drugs and aircraft. Eads & Reuter, *supra* note 44, at 289-90.

should have to allocate only the costs and benefits of technologies whose side effects can credibly be termed surprises or whose benefits and costs are nearly equal.

III. Coordinating the Liability and Regulatory Systems

Health, safety and environmental regulation has developed at the same time that tort law has expanded its coverage of products and environmental impacts. These two responses to contemporary technologies are very different and their relationship demands greater attention. Simple preemption of tort law is not adequate.

Preemption doctrine itself is not attuned to the problem of deterring risks. It was developed to effectuate Congressional intent with respect to federalism and to establish a guideline for courts which must determine whether a federal law or program should override state endeavors in the same field. When a defendant argues that compliance with a federal regulation should be a defense to state common law liability, the question of proper division of federal and state responsibility overlaps with the question of the proper division of judicial and legislative responsibility in the context of a particular legal problem. Even when preemption law applies to a case, however, it does not resolve the difficult issues related to institutional competence to handle risky technologies.

There are several reasons for this. First, while preemption doctrine relies primarily on legislative intent, Congress often has not considered the specific effects of its enactments either on state common law or on the development of a technology and its risks. When courts apply preemption doctrine they treat these omissions as a lack of clarity in the statute and handle the problem as one of statutory interpretation. The *Cipollone* case is a classic example. The majority engaged in a detailed consideration of the way the doctrinal differences between the claims relate to the words used in the statute's preemption provision. The Court wrote as if it were simply carrying out legislative intent, yet it seems apparent that Congress was not really concerned with the kind of distinction the Court was making.[113] The Court's decision carved up the common law in a way which has nothing to do with the real problem of cigarette smoking and its costs. The Court's adherence to preemption doctrine relied on the fiction that Congress had already considered the practical issues at stake.

113. Later courts following *Cipollone* in different statutory contexts have compounded the problem. *See, e.g.*, Stamps v. Collagen Corp., 984 F.2d 1416 (5th Cir. 1993); Tucker v. Collagen Corp., 1994 U.S. Dist. LEXIS 3101 (N.D. Ill. 1994). The courts in these cases found that semantic similarities in preemption language required the same finding of legislative intent regardless of the very different statutory context, subject matter and history. *Cf. supra* note 7 (reasoning of *Cipollone* Court).

Even if the Court's decision is simply a message to Congress to decide these matters, Congress cannot really make specific choices in a context where key knowledge is still unfolding. Congress itself is subject to the same limitations as courts and regulatory agencies. It is rarely in a position to perceive all the ramifications of its enactments. To construe legislative intent broadly is to ignore these limitations. Preemption analysis treats each complex problem as a simple question of divining Congress' managerial strategy, without recognizing the limitations of its managerial resources.

Perhaps the most disturbing aspect of recent preemption decisions in the health and safety context is the line of cases finding preemption of state law for devices that are the focus of special regulatory attention. For instance, some courts have held that medical devices which the FDA has designated as most risky are those most eligible for liability preemption, since the agency will give them more attention than less risky devices.[114] Other decisions have provided more protection against liability for devices handled under special investigation permits than for devices which have proven themselves.[115] Where the FDA has signaled the greatest uncertainty and need for watchfulness, the courts should not restrict plaintiffs' access to discovery and litigation. When courts treat the elaborateness and length of regulations as signifying occupation of the field, they may not read what the agency's words say. Courts should hesitate to find preemption under such circumstances. In

114. The MDA classifies devices by the level of information available about them, their potential to inflict injury, the controls available to assure safety and effectiveness and their medical usefulness. 21 U.S.C. § 360c(a) (1988). Class I devices, which pose little or no threat to health, are subject only to the most general controls. *Id.* § 360c(a)(1)(A). Class II devices, which pose a slightly greater risk to health, warrant postmarket surveillance, patient registries, and performance standards in some cases. *Id.* § 360c(a)(1)(B). Class III devices present a serious risk of injury. These devices are required to undergo a thorough premarket approval process before introduction. *Id.* § 360c(a)(1)(C). Finally, certain devices are given investigational device exemption to encourage innovation and experimentation. *Id.* § 360j(g). In King v. Collagen Corp., 983 F.2d 1130 (1st Cir. 1993), the court found personal injury claims against manufactures of Class III devices more clearly preempted than claims against manufacturers of cigarettes or Class I and II devices.

115. The MDA provides for special treatment of investigational devices. The court in Gile v. Optical Radiation Corp., 22 F.3d 540, 542 (3d Cir. 1994), found that the plaintiff's claims were expressly preempted since investigational devices are regulated as heavily as Class III medical devices. *Id.* at 542. The FDA has issued regulations governing the development of the intraocular lens that require detailed applications and govern every aspect of the investigational program. The *Gile* court followed the reasoning of Slater v. Optical Radiation Corp., 961 F.2d 1330, 1333 (7th Cir. 1991). In *Slater*, Judge Posner held, "Of course the FDA will not grant an investigation-device exemption unless it believes that the device has sufficient promise of being proved safe and effective to justify the risk of it being used on human beings." *Id.* at 1338.

This use of preemption relies on an agency judgment which is unrealistic to expect and which contradicts the FDA's own reading of its process. Judge Posner's opinion cites the legislative history of the MDA, stating that Congress "intended to encourage innovation by exempting promising experimental devices from the normal requirement of establishing the safety and efficacy of a medical device before it can be sold." *Id.* at 1331-2. This result seems incorrect, since the agency had explicitly classified the device as needing caution and more learning.

any event, the entire preemption doctrine is due for serious reconsideration.[116]

When courts rush to find preemption they also ignore fundamental deterrence dynamics, including the place of compensation in the overall legal scheme. Deterrence and compensation are often treated as separable for analytic purposes, but this does not mean that they can easily be separated in practice. In the tort scheme, compensation acts as the fine or tax that enforces the deterrence signal. Compensation attempts to reflect actual social costs,[117] and thus is a basic part of the market's legal infrastructure. Regulation is not designed to provide or account for compensation; usually regulators intend neither to account for it nor to prevent it. If identifying an appropriate cost-benefit allocation were the only legal function with respect to technologies, then we could invoke preemption and dismiss tort claims with apologies to the plaintiffs, the unfortunates who bear the harms imposed by an otherwise acceptable risk-benefit allocation. But if compensation is a part of the deterrence function, then we cannot preempt tort claims without replacing that enforcement mechanism. In this light, tort plaintiffs are proxies for all members of society.

Perhaps the courts' readiness to treat compensation as a separable and secondary function stems from an underlying concern that, if society forces technologies to pay for their social costs, investment in R&D will decline. If this is the true concern, however, there are better solutions than enacting sweeping rearrangements of liability and regulation. We need to explore new designs and doctrines in both regulation and common law to improve our understanding and support of the innovation process. We can better support innovation if we clarify the relationship between regulation and liability.

Some of the literature which advocates regulatory preemption of tort liability aims to refine current institutional arrangements. For example, Susan Rose-Ackerman suggests that tort law and regulation can be complementary when courts see tort doctrines as temporary stopgaps that apply when more stringent regulatory standards are absent. Courts, she argues, should adopt the agency standard to determine negligence liability or should impose true strict liability, simply finding causation and adjudicating damages. Also, when regulations are explicitly intended to set minimum standards, stricter tort standards could supplement them.[118]

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116. *See* Susan Stabile, Preemption of State Law by Federal Law: A Task for Congress or the Courts? (unpublished manuscript in progress, on file with author).

117. *See* Kahn, *supra* note 1, at 1181-3 (arguing that agencies often fail to act on their mandates and that deterrence is ineffective without some penalty or threat of liability).

118. Rose-Ackerman, "*Tort Law in the Regulatory State*," *in* TORT LAW AND THE PUBLIC INTEREST, *supra* note 1, at 80, 86. When courts act as gap fillers, Rose-Ackerman suggests, a problem arises if courts interpret statutes in light of common law principles; they should instead follow the statute's purpose. *Id.* at 87; ROSE-ACKERMAN, *supra* note 100, at 120-29.

This approach is consistent with the predominant view that the legislature is the more legitimate and able lawmaker and that the courts' legitimate role is limited to filling legislative gaps. However, it is possible to conceive of the situation as just the reverse; we can say that regulation actually supplements the bottom line drawn by tort law. Where technologies develop before costs have been recognized, as in the case of a true surprise, or where the recognized costs are outweighed by the benefits, then regulation may be called upon to allocate these costs and benefits.[119] Courts could thereafter simply apply the regulatory standard, while acting as monitors by remaining open to adjudication based upon new information which was not available when the agency acted.

In either perspective, better coordination will require changes in tort law and in regulation. At least two important developments should occur. First, agencies should build upon the lessons of innovation economics and intellectual property law when granting permits and other certifications. Second, both regulation and tort law should focus more on the manner in which knowledge about negative side effects is produced and made available.[120]

Intellectual property law can give some guidance on how agencies should issue standards, permits, and product registrations. Intellectual property and health and safety law are both concerned with the design of technical systems—both are bodies of law concerning technology—so the two should fit and support each other. When agencies or courts find that a true surprise or a true bargain of a product has been developed, then it may be appropriate to preempt liability, but this finding should be made on the basis of a record which specifically addresses the research issues.

Permits affect technical change and the competitive conditions in a market. Just as tort law's promise of liability and patent law's promise of monopoly analogously influence R&D, permits and patents are also analogous. Both certify a technology and thus provide a benefit for its owner. With common law preemption, permit applicants would receive protection from liability that is an advantage vis à vis rivals without permits. Preemption thus could exacerbate entry barriers. Freedom from liability also tends to remove or reduce incentives to improve the technology's health and safety performance.

Regulatory protection from competition or liability should be carefully crafted and should not be indefinite either in scope or duration. Permit entitlements should not be long-term or rigid and should be subject to caveats to cover significant surprises. Today the duration of permits is often set by bureaucratic rules of thumb, chosen for ease of recordkeeping and renegotiated

119. *See* Kahn, *supra* note 1, at 1181.

120. *See* Kahn, *supra* note 1, at 1183-86 (arguing that regulation can be enhanced to improve its own and tort law's performance, and that one way to achieve this is to make regulatory expertise more available to courts).

on the basis of keeping old plants in place to maintain jobs. Both command and control regulation and incentive-based systems attempt to overcome this inertia, the first by setting standards at levels that are appropriately "technology forcing" and the second by making polluting costly enough to generate innovations. However, even if regulatory standards are attuned to factors affecting technical change, removing liability entails risks. Preemption locates at one point in time the judgment about the acceptability of a particular technology. Technological knowledge sometimes changes very abruptly, as new opportunities appear. A permit's time span should relate to the technological prospects and appropriability patterns in the industry. Finally, agencies should be more open to reconsidering regulatory action when new information is available, particularly where firms have withheld or avoided developing data. The Supreme Court in *Cipollone* remarked on the importance of agencies' having all the relevant information available to them. Unless permits address these issues, they freeze the approved technology at a level that is less than efficient immediately after approving the permit. We should take advantage of the improving stock of knowledge by providing for maximum flexibility in permits. Permits should not prevent liability for side effects not considered by the agency.

At the same time, winning a permit should be conditioned upon some contribution to improving knowledge about a technology's side effects, especially in the early stages of its development and use. A firm securing a permit wins the legal right to externalize costs. The permitting agency may or may not know the extent of the transfer it is effecting, that is, the harms it is imposing on the firm's neighbors and consumers. Outside the context of pharmaceuticals and medical devices, firms are usually not required to provide information on the impacts of their products or activities. Most regulation has placed the onus of uncertainty on the public and granted firms the right to pollute when the public could not show sufficient harm to outweigh the benefit. This general allocation of the burden of proof ignores the opportunities to learn about and avoid harms that are available to the producers of technologies.

Permits should not prevent liability for side effects not considered by the agency. Permit applicants should bear some burden to identify and research these effects. Ideally, to justify a regulatory defense, permits should be based explicitly upon a showing that a firm has researched or at least identified the type and scale of its impacts, and that it is contributing to the improvement of the current technology. Ideally, the scope of the permit should be limited to the effects identified and researched. A showing of the environmental usefulness of a product or of reduced impact or exposure should gain the

applicant an advantage over rivals.[121] The food and drug regulatory scheme is currently the only regulatory scheme that attempts to fulfill these standards.

Shifting the general burden of proof need not result in crushing research burdens and greater uncertainty. Given the generative nature of knowledge, we may see a rechannelling of effort, an unravelling of incentives to suppress or avoid information, and increased momentum for solutions to the problem of producing health and safety information.[122] Moreover, we need not rely on producers to describe their own products. Just as the profession of environmental auditing has developed in response to the need for better corporate management of environmental problems, independently accredited and licensed research laboratories and related enterprises could develop. Independent cooperative research could be funded with industry support.[123] Regulation should be designed with these goals in mind.

Common law doctrines should also be reevaluated in light of the innovation literature. A detailed analysis is beyond the scope of this article, but some suggestions seem appropriate. First, courts should not be quick to preempt common law liability and should not dismiss cases based on information claims until there has been some opportunity for discovery of misuse or concealment of information. Courts should not hurry to dismiss lawsuits before discovery. Agencies often cannot tell whether firms have withheld information. Plaintiffs can help here; they have a specific interest in doing so and they can use the discovery rules, with the court's supervision. In addition, courts should impose testing requirements, treat firms as experts, and hold them to the highest standards of care in research and warning. Labelling requirements should be flexible and should only be preemptive in situations where knowledge is well developed and easily understood. Disclosure of product risks should be preferred where development of HSE knowledge may depend upon it.

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121. *See, e.g.*, references in Lyndon, *Secrecy and Innovation*, *supra* note 18, at 53-54; Ashford et al., *supra* note 103.

122. Frank Michelman suggests that environmental control strategies which aim for "zero pollution" and "maximum feasible abatement" make sense if they are seen as attempts to value uncertainty costs and internalize them to their cheapest cost avoider. Frank I. Michelman, *Pollution as a Tort: A Non-Accident Perspective on Calabresi's Costs*, 80 YALE L.J. 647, 685 (1971). However, polluters may not be the cheapest developers of information. Michelman proposes a system of interlocking regulatory and liability options and requirements, some of which are reflected in current law, particularly in California's Safe Drinking Water and Toxic Enforcement Act, CAL. HEALTH & SAFETY CODE §§ 25249.5- 25249.13, also known as Proposition 65. Disclosure of discharges combined with liability for harm with the burden of proof on the discharger shifts the research and regulation incentives. *See also* David Roe, *Barking Up the Right Tree: Recent Programs Focusing the Toxic Issue*, 13 COLUM. J. ENVTL. L. 275-80 (1988); Lyndon, *Information Economics*, *supra* note 18.

123. *See* Lyndon, *Information Economics*, *supra* note 18.

Conclusion

The analysis here situates liability and regulation in the context of technical change. It views both kinds of law in terms of institutional learning capacity—the ability to collect, interpret, and distribute guidance on the development of technology. Rather than asking whether tort law is better than regulation or vice-versa, this Article asks the following questions: What organizational, procedural, and doctrinal methods can appropriately respond to and guide technical change? What capacities should legal institutions have if they are to guide technological development in order to maximize long range social benefits? Should they have any of the characteristics of current tort law? How can the two types of law be better coordinated?

If we focus on knowledge as tangible and concretely produced, we can conceive of health and safety law as serving a learning function, working with intellectual property law to manage the available stock of technical information. Private research is driven by the search for efficacy and tends to ignore or underestimate risks and costs. The law should emphasize incentives to research side effects, but may be even more important where this research yields no early clues. In the situation where side effects are surprising, the law should try to pick up the first signals.

The argument for preemption holds that tort law detracts from regulation's effectiveness, but courts may respond to technological risks in useful ways when legislatures and administrative agencies cannot. In particular, courts can assemble and communicate knowledge which is costly to develop in other ways. The variability and flexibility of the questions that courts ask about technology and the nature of the sources they draw upon make them an important social learning mechanism. The seriousness and type of side effects and the R&D dynamics of a product will vary with its context, so that the ability to give attention to technological problems on a small scale and on a highly contextualized basis is important part of the social system's overall response. Also, tort law's signals contain necessary basic messages that are not delivered through any other medium. An important function of the law is to guide early evolution of technologies so that when we do reach the point of allocating existing costs and benefits, we have already controlled risks to some degree. The tort liability system's way of considering and allocating risks offers advantages that we need to account for before preempting tort law. Particularly where uncertainty is endemic, tort law offers advantages as a learning and feedback mechanism.